ENVIRONMENTAL AND SAFETY IMPACTS OF NANOTECHNOLOGY: WHAT RESEARCH IS NEEDED?

HEARING

BEFORE THE

COMMITTEE ON SCIENCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

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ENVIRONMENTAL AND SAFETY IMPACTS OF NANOTECHNOLOGY: WHAT RESEARCH IS NEEDED?

THURSDAY, NOVEMBER 17, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE,
Washington, DC.

The Committee met, pursuant to call, at 10:00 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Sherwood Boehlert [Chairman of the Committee] presiding.

COMMITTEE ON SCIENCE
U.S. HOUSE OF REPRESENTATIVES

Environmental and Safety Impacts of Nanotechnology: What Research is Needed?

Thursday, November 17, 2005
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building (WEBCAST)

Witness List

Dr. E. Clayton Teague
Director
National Nanotechnology Coordination Office

Mr. Matthew M. Nordan
Vice President of Research
Lux Research Inc.

Dr. Krishna C. Doraiswamy
Research Planning Manager
DuPont Central Research and Development

Mr. David Rejeski
Director, Project on Emerging Nanotechnologies
Woodrow Wilson International Center for Scholars

Dr. Richard Denison
Senior Scientist
Environmental Defense

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HEARING CHARTER

COMMITTEE ON SCIENCE
U.S. HOUSE OF REPRESENTATIVES

Environmental and Safety Impacts of Nanotechnology: What Research Is Needed?

THURSDAY, NOVEMBER 17, 2005
10:00 A.M.—12:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

1. Purpose

On Thursday, November 17, 2005, the Committee on Science of the House of Representatives will hold a hearing to examine current concerns about environmental and safety impacts of nanotechnology and the status and adequacy of related research programs and plans. The Federal Government, industry and environmental groups all agree that relatively little is understood about the environmental and safety implications of nanotechnology and that greater knowledge is needed to enable a nanotechnology industry to develop and to protect the public. The hearing is designed to assess the current state of knowledge of, and the current research plans on the environmental and safety implications of nanotechnology.

2. Witnesses

Dr. Clayton Teague is the Director of the National Nanotechnology Coordination Office, the office that coordinates federal nanotechnology programs. The office is the staff arm of the Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council (NSTC). NSTC includes all federal research and development (R&D) agencies and is the primary coordination group for federal R&D policy.

Mr. Matthew M. Nordan is the Vice President of Research at Lux Research Inc., a nanotechnology research and advisory firm.

Dr. Krishna C. Doraiswamy is the Research Planning Manager at DuPont Central Research and Development, and is responsible for coordinating DuPont's nanotechnology efforts across the company's business units.

Mr. David Rejeski is the Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars.

Dr. Richard Denison is a Senior Scientist at Environmental Defense.

3. Overarching Questions

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

4. Brief Overview

- Nanotechnology is expected to become a major engine of economic growth in the coming years. According to Lux Research,[1] a private research firm that focuses on nanotechnology, in 2014 there could be $2.6 trillion worth of products in the global marketplace which have incorporated nanotechnology—15 percent of manufacturing output. Lux also predicts that in 2014, 10 million manufacturing jobs worldwide—11 percent of total manufacturing jobs—will involve manufacturing these nanotechnology-enabled products.
- There is a growing concern in industry that the projected economic growth of nanotechnology could be undermined by real environmental and safety risks of nanotechnology or the public's perception that such risks exist.
- The small size, large surface area and unique behavioral characteristics of nanoparticles present distinctive challenges for those trying to assess whether these particles pose potential environmental risks. For example, nanoscale materials such as buckyballs, nano-sized clusters of carbon atoms, behave very differently than their chemically-equivalent cousin, pencil lead. There is an unusual level of agreement among researchers, and business and environmental organizations that basic scientific information needed to assess and protect against potential risks does not yet exist.
- In December 2003, the President signed the *21st Century National Nanotechnology Research and Development Act* (P.L. 108–153), which originated in the Science Committee. This Act provided a statutory framework for the interagency National Nanotechnology Initiative (NNI). Among other activities, the Act called for the NNI to ensure that research on environmental concerns is integrated with broader federal nanotechnology research and development (R&D) activities.
- Federal funding for the NNI has grown from $464 million in fiscal year 2001 (FY01) to a requested $1.1 billion in FY06. Of the requested FY06 level, the President's budget proposes that $38.5 million (four percent of the overall program) be directed to research on environmental and safety implications of nanotechnology.

5. Background

The National Academy of Sciences describes nanotechnology as the "ability to manipulate and characterize matter at the level of single atoms and small groups of atoms." An Academy report describes how "small numbers of atoms or molecules. . .often have properties (such as strength, electrical resistivity, electrical conductivity, and optical absorption) that are significantly different from the properties of the same matter at either the single-molecule scale or the bulk scale."[2]

Nanotechnology is an enabling technology that will lead to "materials and systems with dramatic new properties relevant to virtually every sector of the economy, such as medicine, telecommunications, and computers, and to areas of national interest such as homeland security."[3] As an enabling technology, it is expected to be incorporated into existing products, resulting in new and improved versions of these products. Some nanotechnology-enabled products are already on the market, including stain-resistant, wrinkle-free pants, ultraviolet-light blocking sun screens, and scratch-free coatings for eyeglasses and windows. In the longer run, nanotechnology may produce revolutionary advances in a variety of industries, such as faster computers, lighter and stronger materials for aircraft, more effective and less invasive ways to find and treat cancer, and more efficient ways to store and transport electricity.

The projected economic growth of nanotechnology is staggering. In October 2004, Lux Research, a private research firm, released its most recent evaluation of the potential impact of nanotechnology. The analysis found that, in 2004, $13 billion worth of products in the global marketplace incorporated nanotechnology. The report projected that, by 2014, this figure will rise to $2.6 trillion—15 percent of manufacturing output in that year. The report also predicts that in 2014, ten million manufacturing jobs worldwide—11 percent of total manufacturing jobs—will involve manufacturing these nanotechnology-enabled products.[4]

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[1] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.
[2] *Small Wonders, Endless Frontiers: A Review of the National Nanotechnology Initiative,* National Research Council/National Academy of Sciences, 2002.
[3] Id.
[4] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.

6. How Might Environmental and Safety Risks Affect the Commercialization of Nanotechnology?

Lux Research Report on Environmental and Safety Risks of Nanotechnology

In May, 2005, Lux Research published a comprehensive analysis of how environmental and safety risks could affect the commercialization of nanotechnology.[5] While a limited number of studies have been done on specific environmental impacts, the report concludes that the few that have been done raise sufficient cause for concern. This leads to what the report calls a fundamental paradox facing companies developing nanotechnology: "They must plan for risks without knowing precisely what they are." The report then identifies two classes of risk that are expected to effect commercialization: "*real* risks that nanoparticles may be hazardous and *perceptual* risks that they pose a threat regardless of whether or not it is real." The report calculates that at least 25 percent of the $8 trillion in total projected revenue from products incorporating nanotechnology between 2004 and 2014 could be affected by real risks and 38 percent could be affected by perceived risk."

The report describes that varying levels of risk are suspected for different types of nanomaterials and products and for different phases of a product's life cycle. For example, some nanoclay particles raise little initial concern because they would be locked up in composites to be used in automotive bodies. On the other hand, cadmium-selenide quantum dots that could be injected into the body for medical imaging tests are highly worrisome due to the toxicity of cadmium-selenide and the fact that they would be used within the human body.

Another factor that contributes to the potential risk of different nanotechnology-related products is the expected exposure of people and the environment over the product's life cycle.

The manufacturing phase is the first area of concern because workers potentially face repeated exposure to large amounts of nanomaterials.[6] During product use, the actual risk will vary depending in part on whether the nanoparticles have been fixed permanently in a product, like within a memory chip in a computer, or are more bio-available, like in a sun screen where exposure may be more direct or may continue over a long period of time. Finally, the greatest uncertainties exist about the risks associated with the end of a product's life because it is difficult to predict what method of disposal, such as incineration or land disposal, will be used for a given material, and there has been little research on, for example, what will happen to nanomaterials within products stored in a landfill over 100 years.

The Lux Research report finds that nanotechnology also faces significant perceived risks. These risks are driven by people's general concerns about new technologies that they may be exposed to without being aware of it. However, public perceptions of nanotechnology are still up in the air and may be influenced by the press and non-governmental organizations. The report argues that, with a concerted effort to emphasize the benefits of nanotechnology, communicate honest assessments of toxicological effects, and engage all interested stakeholders from the outset, the public could be made comfortable with this new technology.

Woodrow Wilson International Center Study on Public Perceptions

A more in-depth survey of public perception of nanotechnology was recently completed by Woodrow Wilson Center's Project on Emerging Technologies.[7] The study found that the public currently has little knowledge about nanotechnology or about how risks from nanotechnology will be managed. This lack of information can lead to mistrust and suspicion. However, the study shows that when people learned more about nanotechnology and its promised benefits, approximately 80 percent were supportive or neutral about it. Once informed, people also expressed a strong preference for having more information made available to the public, having more testing done before products were introduced, and having an effective regulatory system. They do not trust voluntary approaches and tend to be suspicious of industry. The lesson, according to the report, is that there is still time to shape public perception and to

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[5] Lux Research, "A Prudent Approach to Nanotech Environmental, Health and Safety Risks." May 2005

[6] Lux Research's findings on worker exposure are consistent with the concerns expressed in the recent report on the NNI by the President's Council of Advisors on Science and Technology. The report, *National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel,* is available online at *http://www.nano.gov/FINAL_PCAST_NANO_REPORT.pdf.*

[7] *Informed Public Perception of Nanotechnology and Trust in Government,* Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars is available online at *http://www.pewtrusts.com/pdf/Nanotech_0905.pdf.*

ensure that nanotechnology is developed in a way that provides the public with information it wants and establishes a reasonable regulatory framework.

7. Emerging Environmental and Safety Concerns

Initial research on the environmental impacts of nanotechnology has raised concerns. For example, early research on buckyballs (nano-sized clusters of 60 carbon atoms) suggests that they may accumulate in fish tissue. Although it may turn out that many, if not most, nanomaterials will be proven safe in and of themselves and within a wide variety of products, more research is needed before scientists can determine how they will interact with people and the environment in a variety of situations.

Nanotechnology's potential to affect many industries stem from that fact that many nanoscale materials behave differently than their macroscale counterparts. For example, nano-sized quantities of some electrical insulating materials become conductive, insoluble substances may become soluble, some metals become explosive, and materials may change color or become transparent. These novel features create tremendous opportunities for new and exciting applications, but also enable potentially troubling new ways for known materials to interact with the human body or be transported through the environment. It is difficult and would be misleading to extrapolate from current scientific knowledge on how materials behave in their macro-form to how they will behave in nano-form, and new techniques to assess toxicity, exposure, and ultimately public and environmental risks from these materials may be needed.

Widely Recognized Research and Development Needs

Businesses, non-governmental organizations, academic researchers, federal agencies, and voluntary standards organizations all have efforts underway to address concerns about the environmental and safety implications of nanotechnology. However, a number of organizations, including business associations and environmental groups, worry that environmental R&D is not keeping pace with the rapid commercialization and development of new nanotechnology-related products. There is widespread agreement on the following research and standards needs:

- Nanotechnology needs an accepted nomenclature. For example, "buckyballs" is the equivalent of a trade name; it does not convey critical information about the content, structure, or behavior of nanoparticles as traditional chemical nomenclature does for traditional chemicals. The lack of nomenclature creates a variety of problems. For example, it is difficult for researchers to know whether the nanomaterial they are working with is the same as that presented in other research papers. Similarly, it is difficult for a company to know whether it is buying the same nanomaterial from one company that it previously bought from another.
- Nanotechnology needs an agreed upon method for characterizing particles. Nanoparticles unique size enables unusual behavior. At these small sizes, particles can have different optical and electrical properties than larger particles of the same material. In addition, the large surface area of nanoparticles relative to their mass makes nanoparticles more reactive with their surroundings. Further complicating efforts to characterize nanomaterials is that small changes to some nanoparticles, such as altering the coatings of buckyballs, significantly modify the physical properties (and hence the potential toxicity) of the particles.
- A great deal more information is needed on the mechanisms of nanoparticle toxicity. Early studies suggest that a variety of nanoparticles damage cells through oxidative stress. (Oxidation is believed to be a common source of many diseases such as cancer.) A better understanding of the chemical reactions that nanoparticles provoke or take part in within living organisms will enable researchers to more effectively predict which nanomaterials are most likely to cause problems.
- Basic information on how nanomaterials enter and move through the human body are needed. Early studies point to wide variations in the toxicity of nanomaterials depending on the how exposure occurred—through the mouth, skin contact, inhalation, or intravenously. Particles in the range of 1–100 nanometers are small enough to pass through cell walls and through the blood-brain barrier, making them particularly mobile once they enter the body. There is also concern that some nanoparticles could lodge in the lungs and might be so small as to be overlooked by the body's defense mechanisms that would normally remove these invaders from the body.

- More research is needed on how and why some nanoparticles appear to behave one way as individual particles, but behave differently when they accumulate or agglomerate. One study of buckyballs, for example, found that while individual buckyballs are relatively insoluble, they have a tendency to aggregate, which makes them highly soluble and reactive with bacteria, raising concerns about their transport in watersheds and their impact on ecosystems.

According to a variety of experts, many of whom are familiar with the development of the largely mature databases available on the behavior and toxicity of various chemicals, development of a parallel collection of information on nanotechnology-related materials may take as long as 10–15 years.

Call for a Governmental Program on Environmental and Safety Implications of Nanotechnology

Recently, the American Chemistry Council and the environmental organization, Environmental Defense, agreed on a Joint Statement of Principles that should guide a governmental program for addressing the potential risks of nanoscale materials.[8] They call for, among other things,

- "a significant increase in government investment in research on the health and environmental implications of nanotechnology,"
- "the timely and responsible development of regulation of nanomaterials in an open and transparent process,"
- "an international effort to standardize test protocols, hazard and exposure assessment approaches and nomenclature and terminology,"
- "appropriate protective measures while more is learned about potential human health or environmental hazards," and
- a government assessment of "the appropriateness of or need for modification of existing regulatory frameworks."

8. Federal Government Activities

The National Nanotechnology Initiative (NNI) is a multi-agency research and development (R&D) program begun in 2001 and formally authorized by Congress in 2003.[9] Currently, 11 federal agencies have ongoing programs in nanotechnology R&D, while another 11 agencies participate in the coordination and planning work associated with the NNI. The primary goals of the NNI are to foster the development of nanotechnology and coordinate federal R&D activities.[10]

Federal funding for the NNI has grown from $464 million in FY01 to a requested $1.1 billion in FY06. Of the requested FY06 level, the President's budget proposes that $38.5 million (four percent of the overall program) be directed to research on environmental, health, and safety implications of nanotechnology (see Table 1).[11]

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[8] Environmental Defense and American Chemistry Council Nanotechnology Panel, Joint Statement of Principles, Comments on EPA's Notice of Public Meeting on Nanoscale Materials, June 23, 2005. The full statement is available online at *http://www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf.*

[9] In 2003, the Science Committee wrote and held hearings on the *21st Century National Nanotechnology Research and Development Act,* which was signed into law on December 3, 2003. The Act authorizes $3.7 billion over four years (FY05 to FY08) for five agencies (the National Science Foundation, the Department of Energy, the National Institute of Standards and Technology, the National Aeronautics and Space Administration, and the Environmental Protection Agency). The Act also: adds oversight mechanisms—an interagency committee, annual reports to congress, an advisory committee, and external reviews—to provide for planning, management, and coordination of the program; encourages partnerships between academia and industry; encourages expanded nanotechnology research and education and training programs; and emphasizes the importance of research into societal concerns related to nanotechnology to understand the impact of new products on health and the environment.

[10] The goals of the NNI are to maintain a world-class research and development program; to facilitate technology transfer; to develop educational resources, a skilled workforce, and the infrastructure and tools to support the advancement of nanotechnology; and to support responsible development of nanotechnology.

[11] There is of course additional federal funding being spent on fundamental nanotechnology R&D that has the potential to inform future studies on environmental and safety impacts, so the $38.5 million may be a low estimate of the relevant research underway.

Table 1. NNI Proposed FY2006 Investments in environmental implications ($ in millions)

Agency	Total Spending on Nanotechnology R&D	Environment, Health and Safety Implications R&D	Percent of Total Environment, Health and Safety Implications R&D
NSF	$344	$24.0	62.3
DOD	$230	$1.0	2.6
DOE	$207	$0.5	1.3
NASA	$32	$0.0	0.0
NIH	$144	$3.0	7.8
NIOSH	$3	$3.1	8.1
DOC	$75	$0.9	2.3
USDA	$11	$0.5	1.3
EPA	$5	$4.0	10.4
DOJ	$2	$1.5	3.9
DHS	$1	$0.0	0.0
Total	**$1054**	**$38.5**	**100.0%**

Source: NNI FY 06 Supplement Report: p. 36, 38.

To coordinate environmental and safety research on nanotechnology, the National Science and Technology Council organized in October 2003 the interagency Nanotechnology Environmental and Health Implications Working Group (NEHI WG), composed of agencies that support nanotechnology research as well as those with responsibilities for regulating nanotechnology-based products. NEHI WG is in the process of developing a framework for environmental R&D for nanotechnology that it expects to release in January 2006. To provide useful guidance to agencies, Congress, academic researchers, industry, environmental groups, and the public, the research framework will need to define the scale and scope of the needed research, set priorities for research areas, provide information that can affect agency-directed spending decisions, and be specific enough to serve as overall research strategy for federal and non-federal research efforts.

Currently, over 60 percent of the environmental research funding is provided by the National Science Foundation (NSF). In FY05 and FY06, NSF is putting a small amount of funding (approximately $1 million each year) into a joint solicitation on investigating environmental and human health effects of manufactured nanomaterials with the Environmental Protection Agency, the National Institute for Occupational Safety and Health (NIOSH), and National Institute of Environmental Health Sciences (NIEHS). However, the majority of the NSF's funding in this area is distributed to projects proposed in response to general calls for nanotechnology-related research; projects are selected based on the quality and potential impact of the proposed research. It is not distributed based on the research needs of regulatory agencies such as EPA, OSHA or FDA. Currently NSF and the research community base their understanding of priorities in environmental research on a 2003 workshop "Nanotechnology Grand Challenge in the Environment,"[12] but the federal framework being developed by the NEHI WG should provide helpful, updated guidance for future research solicitations and proposals.

EPA's Office of Research and Development is the second largest sponsor of research on the environmental implications of nanotechnology, providing approximately 10 percent ($4 million) of the federal investment. At the beginning of the NNI, EPA focused its research program on the development of innovative applications of nanotechnology designed to improve the environment, but in FY03, EPA began to shift its focus to research on the environmental implications of nanotechnology. In FY04 and FY05, EPA has increasingly tailored its competitive solicitations to attract research proposals in areas that will inform decisions to be made by the agency's regulatory programs. In January 2006, EPA is planning to release an agency-wide nanotechnology framework that will describe both the poten-

[12] "Nanotechnology Grand Challenge in the Environment: Research Planning Workshop Report," from the workshop held May 8–9, 2003, is available online at *http://es.epa.gov/ncer/publications/nano/nanotechnology4-20-04.pdf.*

tial regulatory issues facing the agency and the research needed to support decisions on those issues.

NIOSH sponsors eight percent ($3 million) of research on environmental and safety implications of nanotechnology, and its activities are driven by the fact that minimal information is currently available on dominant exposure routes, potential exposure levels and material toxicity. NIOSH is attempting fill those gaps by building on its established research programs on ultra-fine particles (typically defined as particles smaller than 100 nanometers). The National Toxicology Program, an interagency collaboration between NIOSH and NIEHS, also supports a portfolio of projects studying the toxicity of several common nanomaterials, including quantum dots, buckyballs, and the titanium dioxide particles that have been used in cosmetics. NIOSH published a draft research strategy in late September 2005.

Private Sector Research

There is little information about how much individual companies are investing in research on the environmental and safety implications of nanotechnology. There are, however, a variety of activities underway in industry associations emphasizing the importance of research in this area. Members of the American Chemistry Council's ChemStar panel, for example, have committed to ensuring that the commercialization of nanomaterials proceeds in ways that protect workers, the public and the environment. Other elements of the chemical and semiconductor industries have formed the Consultive Boards for Advancing Nanotechnology, which has developed a list of key research and evaluation, identifying toxicity testing, measurement, and worker protection.

Potential Regulatory and Policy Issues.

Some companies, especially large firms that operate in many industry sectors, have significant experience dealing with environmental issues and risk management plans, are comfortable dealing with potential environmental and safety implications arising from nanotechnology. However, many companies that are involved with nanotechnology-related products are small, start-up companies or small laboratories with less experience in this area. According to the Lux Research report described above, some of these small enterprises do not carry out testing because they lack the resources to do so, while others do not do so because of fear they might learn something that could create legal liability or create barriers to commercializing their product.

At EPA, the regulatory program offices are trying to determine whether and to what degree existing regulatory programs can and should be applied to nanotechnology. For example, EPA is considering how the Toxic Substances Control Act (TSCA) will apply to nanotechnology, having recently approved the first nanotechnology under that statute. (See Appendix A for a recent Washington Post article discussing the issue). Enacted in 1976, TSCA authorizes EPA to regulate new and existing chemicals and provides EPA with an array of tools to require companies to test chemicals and adopt other safeguards. Decisions on conventional chemicals under TSCA are driven by a chemical's name, test data, and models of toxicity and exposure. Because much of this information does not yet exist for nanotechnology, EPA is having a difficult time deciding how best to proceed. The lack of information led to EPA's recent proposal to create a voluntary program under which companies would submit information that would help the agency learn about nanotechnology more quickly. EPA is now evaluating all of its water, air and land regulatory responsibilities to determine whether and how EPA should handle nanotechnology in these areas.

Other federal agencies with regulatory responsibilities, such as the Food and Drug Administration and the Occupational Safety and Heath Administration, are also trying to determine how they will address environmental and safety concerns related to nanotechnology.

A number of observers, including the United Kingdom's Royal Society,[13] have suggested a precautionary approach to nanotechnology until more research has been completed. They urge caution especially regarding applications in which nanoparticles will be purposely released into environment. Examples of these so-called dispersive uses are nanomaterials used to clean contaminated groundwater or those that when discarded enter the sewer system and thereby the Nation's waterways.

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[13] The United Kingdom's Royal Society and Royal Academy of Engineering's report "Nanoscience and Nanotechnologies: Opportunities and Uncertainties" was published in July 2004 and is available online at *http://www.nanotec.org.uk/finalReport.htm*

9. Witness Questions

The witnesses were asked to address the following questions in their testimony:

Questions for Dr. Clayton Teague

In your testimony, please briefly describe current federal efforts to address possible environmental and safety risks associated with nanotechnology and address the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- How much is the Federal Government spending for research on environmental and safety implications of nanotechnology? Which agencies have the lead? What additional steps are needed?

Questions for Mr. Matthew Nordan

In your testimony, please briefly describe the major findings of the Lux Research report on environmental and safety issues associated with nanotechnology and address the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Dr. Krishna Doraiswamy

In your testimony, please briefly describe what DuPont is doing to address possible environmental and safety risks associated with nanotechnology and answer the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Mr. David Rejeski

In your testimony, please briefly describe the major findings of the Wilson Center's recent study on public perceptions about nanotechnology and answer the following four questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?

- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Dr. Richard Denison

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Appendix A

Nanotechnology's Big Question: Safety
Some Say Micromaterials Are Coming to Market Without Adequate Controls

THE WASHINGTON POST
OCTOBER 23, 2005, PAGE A11
BY JULIET EILPERIN, WASHINGTON POST STAFF WRITER

With little fanfare, the Environmental Protection Agency has for the first time ruled on a manufacturer's application to make a product composed of nanomaterials, the new and invisibly small particles that could transform the Nation's engineering, industrial and medical sectors.

The agency's decision to approve the company's plan comes amid an ongoing debate among government officials, industry representatives, academics and environmental advocates over how best to screen the potentially toxic materials. Just last week, a group of academics, industry scientists and federal researchers, working under the auspices of the nonprofit International Life Sciences Institute, outlined a set of principles for determining the human health effects of nanomaterial exposures.

By year-end, the EPA plans to release a proposal on how companies should report nanomaterial toxicity data to the government.

"Toxicity studies are meaningless unless you know what you're working with," said Andrew Maynard, who helped write the institute's report and serves as chief science adviser to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, a Washington-based think tank.

Because of their tiny size, nanomaterials have special properties that make them ideal for a range of commercial and medical uses, but researchers are still trying to determine how they might affect humans and animals. Gold, for example, may behave differently when introduced at nanoscale into the human body, where it is chemically inert in traditional applications.

The institute's report urged manufacturers and regulators to evaluate the properties of nanomaterials in laboratory tests, adding: "There is a strong likelihood that the biological activity of nanoparticles will depend on physiochemical parameters not routinely considered in toxicology studies."

The EPA decided last month to approve the "pre-manufacture" of carbon nanotubes, which are hollow tubes made of carbon atoms and potentially can be used in flat-screen televisions, clear coatings and fuel cells. The tubes, like other nanomaterials, are only a few ten-thousandths the diameter of a human hair.

Jim Willis, who directs the EPA's chemical control division in the Office of Pollution Prevention and Toxics, said he could not reveal the name of the company that received approval for the new technology or describe how that technology might be marketed. He added, however, that the EPA reserved the right to review the product again if the company ultimately decides to bring it to market.

Nanomaterials are already on the market in cosmetics, clothing and other products, but these items do not fall under the EPA's regulatory domain. EPA officials judge applications subject to the *Toxic Substances Control Act* (TOSCA), a law dating from the mid-1970s that applies to chemicals.

In a Wilson Center symposium last Thursday, Willis said "it is a challenge" to judge nanotechnology under existing federal rules.

"Clearly, [TOSCA] was not designed explicitly for nanoscale materials," he said, but he added that chemicals "have quite a number of parallels for nanoscale materials" and that "in the short-term, we are going to learn by doing."

Scientific studies also suggest nanoparticles can cause health problems and damage aquatic life. For instance, they lodge in the lungs and respiratory tract and cause inflammation, possibly at an even greater rate than asbestos and soot do.

"Nanoparticles are like the roach motel. The nanoparticles check in but they don't check out," said John Balbus, health program director for the advocacy group Environmental Defense. "Part of this is a societal balancing act. Are these things going to provide such incredible benefits that we're willing to take some of these risks?"

Nanomaterials have possible environmental advantages as well. For instance, they can absorb pollutants in water and break down some harmful chemicals much more quickly than other methods.

"Just because something's nano doesn't mean it's necessarily dangerous," said Kevin Ausman, Executive Director of Rice University's Center for Biological and Environmental Nanotechnology. He added that when it comes to nanotechnology's toxic effects, "we're trying to get that data before there's a known problem, and not after there's a known problem."

Companies such as DuPont are pushing to establish nanotechnology safety standards as well, in part because they have seen how uncertainties surrounding innovations—such as genetically modified foods—have sparked a backlash among some consumers.

"The time is right for this kind of collaboration," said Terry Medley, DuPont's Global Director of corporate regulatory affairs. "There's a general interest on everyone's part to come together to decide what's appropriate for this technology."

Chairman BOEHLERT. The hearing will come to order.

I want to welcome everyone to this important hearing on the environmental and safety implications of nanotechnology, an issue that is likely to get increasing public attention over the next several years, but it is a matter that already has claimed the attention of this committee, and it did so some time ago.

As I think everyone knows, the Science Committee has been a leader in pushing the Federal Government to invest in nanotechnology, and in creating the statutory structure to be sure that we stay focused on nanotechnology research and development in a productive way. Our *National Nanotechnology Research and Development Act,* which the President signed just four years ago, made it clear that nanotechnology R&D had to include research on the environmental implications of the technology, not as a sideline, but as a fundamental, integrated part of the research program, and we have been watching closely to make sure that happens.

The need for more research on the environmental and safety aspects of nanotechnology is made amply clear by our non-governmental witnesses this morning, who speak in their written testimony with remarkable unity. Boy, that is refreshing to hear from this side. Their message is clear, and it must be heeded: if nanotechnology is to fulfill its enormous economic potential, then we have to invest more right now in understanding what problems the technology might cause.

This is the time to act, before we cause problems. This is the time to act, when there is a consensus among government, industry, and environmentalists. As Mr. Rejeski says in his testimony, this is our chance to get it right, to learn from past mistakes we made with new technologies.

The writer Kurt Vonnegut once defined the information revolution as the idea that people could actually know what they are talking about, if they really want to. That is exactly the kind of information revolution we need in nanotechnology.

I am pleased to say that the Administration also seems to feel that way, as Dr. Teague will describe this morning. But we need an even greater commitment from the Administration on this issue. We will be closely reviewing the so-called framework on this matter that is due out early next year, as well as the fiscal 2007 budget request due out in February, to ensure that funding is adequate.

So, let me close by thanking our witnesses at the outset for the excellent, clear, and persuasive testimony they have prepared for today's hearing. This is exactly the kind of hearing that the Science Committee should be having, and that only we are likely to have, that is, bringing attention to an important issue before it becomes a crisis, before it becomes hopelessly polarized, before all the debate becomes depressingly predictable.

So I look forward to today's hearing, and I promise you that we will continue to press forward with this issue.

With that, the Chair is pleased to recognize Mr. Gordon of Tennessee.

[The prepared statement of Chairman Boehlert follows:]

PREPARED STATEMENT OF CHAIRMAN SHERWOOD L. BOEHLERT

I want to welcome everyone to this important hearing on the environmental and safety implications of nanotechnology—an issue that is likely to get increasing public attention over the next several years. But it's a matter that has already claimed the attention of this committee for some time.

As I think everyone knows, the Science Committee has been a leader in pushing the Federal Government to invest in nanotechnology and in creating the statutory structure to be sure that we stay focused on nanotechnology research and development (R&D) in a productive way. And our *National Nanotechnology Research and Development Act,* which the President signed four years ago, made it clear that nanotechnology R&D had to include research on the environmental implications of the technology—not as a sideline, but as a fundamental, integrated part of the research program. And we have been watching closely to make sure that happens.

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So I look forward to today's hearing, and I promise you that we will continue to press forward with this issue.

Mr. GORDON. Thank you, Mr. Chairman, and once again, let me say I want to concur with your opening statement.

Also, I feel there is no question that this committee understands the importance of nanotechnology, and recognizes the strong justification for a robust federal research investment. The Committee has held several hearings to evaluate the promise of nanotechnology. In 2003, the Committee took the lead in passing the *21st Century Nanotechnology Research and Development Act,* which is now funded at over $1 billion a year.

However, from the outset, we also recognized that risks may arise from this technology; this is the subject of today's hearing. Some research has suggested that nanoparticles could cause human health problems, and may damage aquatic life, but research in this area is in its infancy, and the tools are not available to identify and assess the risks associated with nanomaterials, yet many products containing nanoparticles are already on the market, in cosmetics, clothing, and other products. Some estimates are that there are as many as 700 products already on the market.

Maybe there are no harmful effects. We simply do not know the necessary information to know if there are or aren't. What is clear is the commercialization of the technology is outpacing the development of science-based policies to assess and guard against adverse

environmental health and safety consequences. The horse is already out of the barn. Thus, prudence suggests the need for urgency in having the science of health and environment implications catch up to or even better, surpass the pace of commercialization. We need to develop the tools and procedures to determine if nanomaterials are harmful, and if so, what specific controls may be needed.

From the beginning, the National Nanotechnology Initiative has included funding for research to address environment, health, and safety aspects of the technology, but funding levels have been fairly anemic. At present, the total funding in this area is under $40 million for the $1.1 billion initiative, and the majority of the funding is concentrated at the National Science Foundation, and while I applaud the National Science Foundation's efforts, I am concerned that other key agencies remain minor players. For example, related funding at the Environmental Protection Agency is only $4 million.

So, the main questions I have here are: Is environment, health, and safety research directed toward the most and important priorities? Is it funded at appropriate level, and do all communities of interest have a voice in establishing the research goals and the priorities? I also encourage any suggestions our witnesses may have on ways to improve the environment, health, and safety component of the National Nanotechnology Initiative.

And following up on our chairman's concern about nanotechnology reaching its full potential, I think it is very important that we understand these issues, not only to protect ourselves, in terms of whatever health impact there might be, but also, in what you might call marketing. We have seen how genetically altered foods, in most situations, I think folks would say that they are healthy and safe, yet there has been resistance in the public in many parts of the world to these products, because that research came behind the actual products. So, if we are going to have successful commercialization, and make the best use of these nanotechnology products, then it is important that the public know well up front that they are safe, or if they are not safe, where they are not, and how that can be corrected. So, I hope we can learn more about that today.

And thank you, Mr. Chairman, for calling this hearing.

[The prepared statement of Mr. Gordon follows:]

PREPARED STATEMENT OF REPRESENTATIVE BART GORDON

I want to join Chairman Boehlert in welcoming everyone to this morning's hearing. There is no question that this committee understands the importance of nanotechnology and recognizes the strong justification for a robust federal research investment.

The Committee has held several hearings to evaluate the promise of nanotechnology. And in 2003, the Committee took the lead in passing the *21st Century Nanotechnology Research and Development Act,* which is now funded at over $1 billion per year.

However, from the outset, we also recognized that risks may arise from this technology, and that is the subject of today's hearing. Some research has suggested that nanoparticles could cause human health problems and may damage aquatic life. But research in this area is in its infancy, and the tools are not available to identify and assess the risks associated with nanomaterials.

Yet, many products containing nanoparticles are already on the market—in cosmetics, clothing and other products. Some estimate their presence in as many as

700 products. Maybe there are no harmful effects. We simply do not have the necessary information to know if there are or if there aren't.

What is clear is that commercialization of the technology is outpacing the development of science-based policies to assess and guard against adverse environmental, health and safety consequences. The horse is already out of the gate.

Thus, prudence suggests the need for urgency in having the science of health and environmental implications catch up to, or even better surpass, the pace of commercialization.

We need to develop the tools and procedures to determine if nanomaterials are harmful, and if so, what specific controls may be needed.

From its beginnings, the National Nanotechnology Initiative has included funding for research to address environment, health and safety aspects of the technology. But funding levels have been fairly anemic.

At present, total funding in this area is under $40 million for the $1.1 billion initiative, and the majority of that funding is concentrated at the National Science Foundation. While I applaud NSF's efforts, I am concerned that other key agencies remain minor players. For example, related funding at the Environmental Protection Agency is only $4 million.

The main questions I have today are:

- is environment, health and safety research directed toward the most important priorities,
- is it is funded at an appropriate level, and
- do all communities of interest have a voice in establishing the research goals and directions?

I also encourage any suggestions our witnesses may have on ways to improve the environment, health and safety component of the National Nanotechnology Initiative.

Thank you, Mr. Chairman, for calling this hearing. I look forward to the insights that this expert panel will provide today.

Chairman BOEHLERT. And thank you very much, Mr. Gordon, and thank you for your partnership. We are together on this important subject.

[The prepared statement of Mr. Ehlers follows:]

PREPARED STATEMENT OF REPRESENTATIVE VERNON J. EHLERS

Thank you Chairman Boehlert. I am pleased that the Committee is holding this important hearing today.

The promise of nanotechnology is startling. Benefits are anticipated in every facet of our lives; medicine, energy production, and electronics may be revolutionized by nanotechnology. But with this promise, there is also growing concern that the potential short and long-term impacts of nanomaterials on people and the environment are largely unknown. The very properties that make nanomaterials so promising in applications—their small size, large surface area, and unusual behavior when compared to their macro-scale materials—make them potentially troubling when they come in contact with people and the environment. That is why today's hearing is so important.

I look forward to hearing today from our witnesses about these potential risks. What do we know now about these risks? What additional research is needed? What are the Federal Government and the private sector doing to answer these questions? Are we looking at the potential risks across the entire life cycle of nanomaterials—manufacture, use and disposal?

As we move forward with our federal investments in nanotechnology, we need to maintain the public's trust. That will require smart investments in research, accurate assessments of risk, and steady communication with the public about what researchers know and don't know. It will also require that environmental research and an appropriate regulatory framework for nanotechnology keep pace with the rapid growth of innovation and discovery. Without open communication and a trustworthy regulatory framework, misinformation and unfounded fear could undermine the potential economic rewards of nanotechnology.

I am happy that our witnesses represent a cross-section of stakeholders, because cooperation will be a necessary part of both conducting research and sharing its results with the public. I look forward to hearing from our witnesses about how much we know on this topic and how much we still have to learn. Mr. Chairman, I yield back the balance of my time.

[The prepared statement of Mr. Costello follows:]

PREPARED STATEMENT OF REPRESENTATIVE JERRY F. COSTELLO

Good morning. I want to thank the witnesses for appearing before our committee to examine current concerns about environmental and safety impacts of nanotechnology and the status and adequacy of related research programs and plans.

Relatively little is understood about the environmental and safety implications of nanotechnology. The lack of knowledge about the effects of nanoparticles and the absence of established methods to assess their impacts on the environment and human health is troubling since nanomaterials are already on the market in cosmetics, clothing and other products. Further, there are no established scientific protocols for either safety or environmental compatibility testing for nanomaterials.

I am pleased we are having this hearing today because greater knowledge is needed to enable a nanotechnology industry to develop and to protect the public. Regulation for certain types of applications of nanomaterials could eventually be needed and Congress needs more information on the environmental and safety impacts of nanotechnology to better protect the public.

I look forward to hearing from the panel of witnesses.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF REPRESENTATIVE EDDIE BERNICE JOHNSON

Thank you, Mr. Chairman and Ranking Member.

I would like to extend a warm welcome to today's witnesses and thank them for engaging in a discussion on the potential health risks and environmental impacts of nanomaterials.

Scientists at the University of Texas at Dallas have produced transparent carbon nanotube sheets that are stronger than the same-weight steel sheets and can be used for organic light-emitting displays, electronic sensors, artificial muscles, and broad-band polarized light sources that can be switched on one ten-thousandths of a second.

In the August 19th issue of the prestigious journal *Science,* scientists from the NanoTech Institute at UTD and a collaborator reported such assembly of nanotubes into sheets at commercially usable rates.

This development is significant. I have always advocated in favor of increased support for research, and I feel that we should carefully consider the health and environmental impacts of nanotechnology in general.

I am interested to know the status of research in this area and how the Congress can direct policies to support this research.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Honda follows:]

PREPARED STATEMENT OF REPRESENTATIVE MICHAEL M. HONDA

I thank the Chairman and Ranking Member for holding this important hearing today. On our side of the aisle, we have been talking about environmental, health, and safety impacts of nanotechnology since the Committee first considered nanotechnology legislation. Our former colleague, Mr. Bell, offered amendments to focus work on toxicological studies and environmental impact studies and to set aside funding for environmental research and development, but unfortunately the Administration opposed these efforts and thus Members from the other side moved in lock step to oppose those amendments.

I'm glad those on the other side have finally come to realize that we need to talk about this aspect of nanotechnology too, in addition to the enormous potential that it has for good. I expect that the witnesses will note in their testimony that we are not spending enough on environmental, health, and safety research, and I hope that this will finally wake everyone up to the need to invest in these areas.

Nanotechnology is exciting because of the novel and interesting properties that arise when things get very small. Aircraft parts can be made lighter, computer logic circuits can be made faster, and pants can be made moisture and stain resistant. But the same effects that lead to novel properties at the nanoscale also have the potential to cause problems. Nanoparticles are on the same length scale as biological systems, meaning that they can pass through cell walls. Some early experiments in which fish were exposed to nanoscale carbon have found accumulation of the nanomaterials within the fish and some brain damage. While those experiments

were not indicative of what a typical exposure might be, they certainly draw attention to the need for more study of the potential health impacts of these materials.

Industry is wary about the uncertainty associated with these materials—it is difficult to ascertain what the potential impacts might be, and so it is hard to know what precautions to take or even what research needs to be done. Because of this, EPA and other regulatory agencies are on uncertain footing, unsure about whether existing law such as the *Toxic Substances Control Act* can be applied effectively to nanotechnology or whether new regimes will be needed. All of this uncertainty impacts the willingness of investors to support nanotechnology companies and may impact the willingness of consumers to purchase nanotechnology products.

We are still at the nascent stages of this technology, and so the time to focus on environmental, health, and safety impacts is now, when we can still head off potential problems. If we wait much longer, we may find ourselves in a situation where we have "let the cat out of the bag" and we need to take drastic measures in response.

I look forward to hearing the thoughts of the witnesses on what we should be focusing on and the amount of resources we need to be dedicating to this effort.

[The prepared statement of Mr. Carnahan follows:]

PREPARED STATEMENT OF REPRESENTATIVE RUSS CARNAHAN

Chairman Boehlert and Ranking Member Gordon, thank you once again for hosting this hearing. Dr. Teague, Mr. Nordan, Dr. Doraiswamy, Mr. Rejeski, and Dr. Denison, thank you for taking the time and effort to appear before us today and share your views on the environmental and safety implications of nanotechnology.

Nanotechnology holds great promise in the area of materials and manufacturing, information technology and medicine. I am eager to see what this technology can do for our nation's health and am hopeful that the utilization of nanotechnology will someday positively affect our economy and job market.

Still, I am very concerned that studies have shown nanoparticles can penetrate deep into the lung, causing tissue damage, and can also settle in the nasal passages, carried directly into brain cells. Clearly, these limited studies require us to conduct further research. I am pleased that there is general consensus among industry and environmental groups that more research on the subject is needed.

Thank you for your time today. I look forward to hearing your testimony.

[The prepared statement of Ms. Jackson Lee follows:]

PREPARED STATEMENT OF REPRESENTATIVE SHEILA JACKSON LEE

The National Academy of Sciences describes nanotechnology as the "ability to manipulate and characterize matter at the level of single atoms and small groups of atoms." An Academy report describes how "small numbers of atoms or molecules. . .often have properties (such as strength, electrical resistivity, electrical conductivity, and optical absorption) that are significantly different from the properties of the same matter at either the single-molecule scale or the bulk scale.

Nanotechnology is an enabling technology that will lead to "materials and systems with dramatic new properties relevant to virtually every sector of the economy, such as medicine, telecommunications, and computers, and to areas of national interest such as homeland security." As an enabling technology, it is expected to be incorporated into existing products, resulting in new and improved versions of these products. Some nanotechnology-enabled products are already on the market, including stain-resistant, wrinkle-free pants, ultraviolet-light blocking sun screens, and scratch-free coatings for eyeglasses and windows. In the longer run, nanotechnology may produce revolutionary advances in a variety of industries, such as faster computers, lighter and stronger materials for aircraft, more effective and less invasive ways to find and treat cancer, and more efficient ways to store and transport electricity.

The projected economic growth of nanotechnology is staggering. In October 2004, Lux Research, a private research firm, released its most recent evaluation of the potential impact of nanotechnology. The analysis found that, in 2004, $13 billion worth of products in the global marketplace incorporated nanotechnology. The report projected that, by 2014, this figure will rise to $2.6 trillion—15 percent of manufacturing output in that year. The report also predicts that in 2014, ten million manufacturing jobs worldwide—11 percent of total manufacturing jobs—will involve manufacturing these nanotechnology-enabled products.

The report describes that varying levels of risk are suspected for different types of nanomaterials and products and for different phases of a product's life cycle. For

example, some nanoclay particles raise little initial concern because they would be locked up in composites to be used in automotive bodies. On the other hand, cadmium-selenide quantum dots that could be injected into the body for medical imaging tests are highly worrisome due to the toxicity of cadmium-selenide and the fact that they would be used within the human body.

Another factor that contributes to the potential risk of different nanotechnology-related products is the expected exposure of people and the environment over the product's life cycle. The manufacturing phase is the first area of concern because workers potentially face repeated exposure to large amounts of nanomaterials. During product use, the actual risk will vary depending in part on whether the nanoparticles have been fixed permanently in a product, like within a memory chip in a computer, or are more bio-available, like in a sun screen where exposure may be more direct or may continue over a long period of time. Finally, the greatest uncertainties exist about the risks associated with the end of a product's life because it is difficult to predict what method of disposal, such as incineration or land disposal, will be used for a given material, and there has been little research on, for example, what will happen to nanomaterials within products stored in a landfill over 100 years.

I look forward to the testimony of our witnesses.

Chairman BOEHLERT. Just to set the stage, let me recite a couple of figures that I think will get your attention. The National Nanotechnology Initiative has grown from $464 million in Fiscal Year 2001, $464 million, to a requested, in the Administration's budget, $1.1 billion for Fiscal Year '06. The Lux Research study is very, very interesting, the Lux study found that in 2004 $13 billion worth of products in the global marketplace incorporated nanotechnology. That same report projects by 2014, just 10 years, that figure will rise to $2.6 trillion. Fifteen percent of the projected manufacturing output in 2014. The report also predicts that in 2014, 10 million manufacturing jobs, or 11 percent of total manufacturing jobs around the globe, will involve manufacturing these nanotechnology-enabled products. Enormous, enormous. You can see why it has our attention.

With that, let me welcome our first panel of very distinguished witnesses, and thank you at the outset for being facilitators for, and resources for this committee. Dr. Clayton Teague, Director, National Nanotechnology Coordination Office. Mr. Matthew Nordan, Vice President of Research, in the aforementioned Lux Research. Dr. Krishna Doraiswamy, Research Planning Manager, DuPont Central Research and Development. Mr. David Rejeski, Director, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. And finally, Dr. Richard Denison, Senior Scientist from Environmental Defense.

Gentlemen, it is a pleasure to have you here. We would ask that in your opening statements, that you try to summarize in five minutes or so. We will not be that arbitrary. We are not going to interrupt you in mid-sentence, mid-paragraph, or mid-thought, but if you would condense your opening statements, your full statements will be inserted in the record at this juncture, but if you try to summarize and capsulize your thinking, that allows for more dialogue between the two of us. And one of the things I have learned after many years of experience on Capitol Hill, when we have distinguished panelists like you, it is a great opportunity for us to learn a lot.

With that, Dr. Teague, you are up first.

STATEMENT OF DR. E. CLAYTON TEAGUE, DIRECTOR, NATIONAL NANOTECHNOLOGY COORDINATION OFFICE

Dr. TEAGUE. Good morning. Mr. Chairman and Members of the Committee, thank you for inviting me to testify at this hearing. I am certainly honored by your invitation.

Let me say at the outset that I and all members of the Nanoscale Science Engineering and Technology Subcommittee, which I will refer to as NSET, appreciate greatly the productive relationship that we have had with Chairman Boehlert and his staff. These relationships have been very supportive in advancing all aspects of the NNI, and so I want to say a very hearty thank you on behalf of everyone.

It is a privilege for me also to speak on behalf of the 24 agencies that participate in the NNI, and their representatives on the NSET Subcommittee. For the past two and a half years, I have had the opportunity of working with staff members from these agencies, and from that experience, I want to assure you that they are sincerely dedicated to the missions of their agencies, particularly including protecting public health and the environment.

Nanotechnology is a truly transformational technology, promising, as you have just said, widespread applications in many fields, ranging from energy and medicine to agriculture and manufacturing. With such a powerful promise, the Administration is committed to fostering this emerging technology. The Administration is equally committed to achieving these benefits in a responsible manner, which means including strong considerations of the environmental health and safety, I will just use the acronym, "EHS," implications from now on. Toward this end, one of the overarching goals of the NNI, as stated in its strategic plan, is to support the responsible development of this new field.

Concerning the subject of this hearing, there are three key messages that I would like to leave you with today. First, the agencies involved in the NNI are working together in a very proactive way, and we have put in place broad and strong coordination in planning activities to understand and address the environmental, health, and safety implications of nanotechnology.

Second, through the NNI, the Federal Government is funding forefront EHS research, and much progress in understanding the EHS implications have been made. Finally, the NNI is supporting studies that are providing useful preliminary information, but as again, you have just indicated, much research is still needed. In all these efforts, the NNI is engaged and coordinating with industry, and other countries to promote the responsible development of nanotechnology.

In the limited time of my oral testimony today, I can only provide a few examples of our efforts to put in place an effective process to deal with the EHS implications of this technology. Let me just give you several of those. First of all, the NSET Subcommittee members' agencies have committed about $39 million in Fiscal Year 2006 to fund research whose primary purpose, let me just repeat that, whose primary purpose is to understand and address the EHS implications of nanotechnology.

Wide ranging research is underway, and new results are coming in almost every day about this area. Within the NSET Sub-

committee, we formed a subgroup that has been active since August of '03, to identify and establish priorities for research needs that support regulatory decision-making. This working group has participation from some 50 members, again, from 24 federal agencies, and it has proven to be an extremely effective forum for communication and coordination among the research and regulatory agencies. Regulatory authorities have been identified and stated publicly, certainly on the FDA website, the Consumer Product Safety Commission's website, and the National Institute of Occupational Safety and Health.

Preliminary recommendations for working safely with engineered nanoparticles have been published by the National Institute for Occupational Safety and Health, to address concerns about working with free nanomaterials in the workplace. And one of the handouts today is that particular document, called "Working with Safe Nanotechnology." Regulatory actions have been taken, and voluntary programs are being formulated. For example, EPA is seeking stakeholder input for nanoscale materials underneath the *Toxic Substance Control Act.* Collaboration with industry is ongoing, through the NSET working groups, with industry-based collaborative boards for advancing nanotechnology, which addresses two or more of the major industrial sectors involved with nanotechnology. International partnerships and cooperation have begun in the area of standardization, including the International Standardization Organization, the American National Standards Institute, the Organization for Economic and Cooperative Development, and ASTM International.

In conclusion, we know that much more research needs to be done, and many questions remain unanswered. Answers will not come quickly, especially on a subject this complex. Research aimed to get answers will require a carefully designed and coordinated plan, with shared government and industry responsibility and collaboration. We must evaluate research very carefully, and if we discover that there are dangers associated with specific uses of certain materials, we should determine what precautions and restrictions will be necessary, including applying and adapting current regulatory authorities. Above all, we need to be guided by data and science-based decisions. Finally, we need to, and we intend to communicate effectively and openly with the public. Nothing else will establish trust and credibility.

Thank you for the opportunity to speak today on this most important aspect of nanotechnology, and I will be happy to answer any of your questions.

[The prepared statement of Dr. Teague follows:]

PREPARED STATEMENT OF E. CLAYTON TEAGUE

Introduction

Mr. Chairman and Members of the Committee, thank you for inviting me to testify at this hearing. I consider it a high honor. My name is Clayton Teague and I am the Director of the National Nanotechnology Coordination Office (or NNCO). The NNCO provides technical and administrative support to the Nanoscale Science, Engineering, and Technology (or NSET) Subcommittee of the National Science and Technology Council's Committee on Technology. The NSET Subcommittee is the interagency body that coordinates, plans, and manages the National Nanotechnology Initiative (or NNI). It is a privilege for me to speak on behalf of all of the 24 agencies that participate in the NNI and representatives on the NSET Subcommittee.

For the past two and a half years, I've had the opportunity of working with staff members of these agencies; I assure you they are sincerely dedicated to the missions of their agencies—including protecting public health and the environment. Many of them unselfishly and intentionally have devoted their entire professional careers to these worthy purposes. My testimony today reflects and is a tribute to their efforts and initiative.

The message that I want to communicate to you today is that the agencies participating in the NNI are working together proactively and have put in place broad and strong coordination and planning activities to understand and address the environmental and safety implications of nanotechnology. Through the NNI, the Federal Government is funding forefront environmental, health, and safety (EHS) research to establish a strong foundation and much progress in understanding EHS implications has been made. In this effort, the NNI is engaged and coordinating with industry and other countries to promote the responsible development of nanotechnology. Finally, NNI-supported studies are providing useful preliminary information, but more research is needed.

Nanotechnology is the understanding, control, and use of matter at dimensions of roughly one to 100 nanometers, where unique phenomena enable novel applications. It is a truly transformational technology, promising widespread applications in many fields, ranging from energy and medicine to agriculture and manufacturing. As these applications move from the laboratory to practical use, nanotechnology has the potential to help strengthen the economy, protect homeland and national security, improve public health and the environment, and raise the quality of life for all people.

With such powerful promise, the Administration is committed to fostering this emerging technology. The Administration is equally committed to achieving these benefits in a responsible manner—including consideration of benefits and possible negative environmental and safety implications. (In the updated NNI Strategic Plan released in 2004, one of the four overarching goals is to "support responsible development of nanotechnology.") We are here today to discuss these implications, and the research that is needed to address them.

Since it was launched in 2000, the NNI has recognized the need to evaluate the environmental and safety implications of this promising technology. As the efforts to develop new nanoscale materials and devices have grown, so too have efforts aimed at improving our understanding of novel properties of nanomaterials, and risks that may arise from those properties. This increased understanding has in turn guided the agencies' research programs on environmental, health, and safety (or EHS) implications of nanotechnology.

These research programs should continue to be performed concurrently with other nanotechnology research. The United States' investment in nanotechnology research represents only one quarter on the investment by governments worldwide. The global pace of innovation is accelerating and other nations are not going to voluntarily slow down in their efforts to reap the potential of nanotechnology. The current approach whereby EHS research is informed by and performed concurrently with scientific, product and process research will ensure that environment and safety concerns are addressed, while maximizing progress toward realizing nanotechnology's economic and societal value to the Nation.

I want to make two points at the outset.

1. Most nanotechnology-based products pose little chance for public exposure and therefore pose little risk to health or the environment. Most uses of nanotechnology today are in composites where the nanoparticles are bound in a matrix (e.g., in golf clubs or car bumpers) or in nanoscale structures that are part of larger devices (e.g., in electronic circuits). Contact with these items generally poses no greater risk than with the versions not containing engineered nanomaterials. Concern is focused on possible risk due to exposure to the relatively small number of end-use products that contain "free" (i.e., unbound) engineered nanomaterials, which may be inhaled, ingested, or absorbed through the skin or that may find their way into the air, soil, or aqueous environment.

2. Manufacturers already minimize exposure to fine particles in the workplace. The greatest likelihood of exposure to engineered nanomaterials is during manufacture (of nanoparticles or using nanoparticles). It is widely known that inhalation of fine particles in conventional industrial operations should be avoided, and the Federal Government, particularly National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA), provides guidance that covers areas such as design and use of ventilation systems, personal protective equipment use, and laboratory practices to minimize such exposure in the workplace. Therefore, minimizing inhalation and dermal exposure to engineered

nanomaterials is recommended and the principles guiding efforts to limit exposure should be very similar to those used to limit exposure to other fine particles.

The purpose of these points is not to downplay potential risks associated with nanotechnology, but to put these issues in context. Exposure to free engineered nanomaterials (as opposed to fine particles that are naturally occurring or that are the incidental byproducts of human activities such as combustion or welding) is for the most part still low. So we are well positioned to assess possible risks before nanoparticles become widely used or make their way into the environment in large quantities.

So what is the Federal Government doing to understand and address the possible risks of nanotechnology to people and the environment?

The agencies participating in the NNI are working together proactively and have put in place broad and strong coordination and planning activities to understand and address the environmental and safety implications of nanotechnology.

Within our interagency NSET Subcommittee, a number of subgroups have been established to address specific areas of interest or concern. One of these subgroups—established in 2003—is the Nanotechnology Environmental and Health Implications (NEHI) Working Group. NEHI brings together representatives from some 24 agencies that support nanotechnology research or that have regulatory responsibilities to exchange information and to identify, prioritize, and implement research needed to support regulatory decision-making processes. Through the efforts of the NEHI Working Group, regulatory agencies have been proactively engaged with each other and the research agencies, leading to earlier awareness of relevant issues and expedited activities to address them. In addition, those agencies that are primarily focused on research have a greater appreciation for the issues confronted by the regulatory bodies.

As an aside, many NEHI Working Group members have commented on how unusual it is for issues to be discussed among the regulatory agencies, much less with research agencies. In remarks before a National Academies panel, Norris Alderson, FDA Associate Commissioner for Science, noted that in his more than 30 years with the FDA, he does not recall the regulatory agencies sitting down together to discuss a subject that crosses regulatory boundaries and authorities before he did so in the NEHI Working Group.

Currently, the NEHI Working Group is developing a coordinated approach to nanotechnology research in the area of environmental, health, and safety (EHS). With input from industry and other non-governmental groups, the Working Group is preparing a document that identifies and prioritizes information and research needs in this area. The document will serve as a guide to the NNI agencies as they develop budgets and programs and will inform individual investigators as they consider their research directions. It will also provide a measure of confidence on the part of policy-makers, such as you, and the public. We look forward to sharing this document with this committee when it is complete.

The NSET Subcommittee has also formed a formal working group to liaise with various industrial sectors, including both the chemical and semiconductor industries. Through these activities, industry is providing input to the NNI regarding precompetitive and non-competitive research needs that those industries deem critical to the successful transition of nanotechnology. Both of these industrial sectors have identified EHS research as an important area for government and industry research, and their input will inform the NEHI Working Group efforts to plan and coordinate NNI programs on the subject.

Finally, the NSET Subcommittee supports a number of international activities related to the topic of nanotechnology and EHS. Concerns about possible environmental and safety implications of nanomaterials are not confined to the United States; research needs are universal. Sharing of information, coordination of research agendas, and collaboration on non-competitive issues benefits everyone. The NNI activities are coordinated through the informal Global Issues in Nanotechnology Working Group, formed in 2005 and led by the State Department.

Through the NNI, the Federal Government is funding forefront EHS research to establish a strong foundation and much progress in understanding EHS implications has been made.

As stated in the NNI Supplement to the President's FY 2006 Budget, the NNI will support nearly $39 million this year on research and development whose *primary purpose* is to understand and address potential risks to health and the environment posed by exposure to nanomaterials and nanoproducts. This estimate does

not include considerable research that is taking place as part of efforts that help advance understanding of nano-EHS implications but that are not focused primarily in this area. For example, many projects funded by the National Institutes of Health to develop nanomaterials for therapeutic applications routinely include basic toxicity testing, although such testing is not the primary purpose of the research. Moreover, this estimate does not include substantial investment in research on the effects of incidental ultra-fine and nano-particles, such as diesel exhaust and power plant emissions.

The NNI research on environmental and health implications is being funded by several agencies, including EPA, NIOSH, NSF, NIH, NIST, USDA, DOD, and DOE. Where appropriate, agencies are working together in a carefully coordinated effort to address research areas that fall within more than one agency's mission or that require multiple agencies' expertise.

Examples of multi-agency activities include:

- EPA, NSF, NIOSH, and NIEHS plan to issue a joint solicitation to support approximately $8 million of research on environmental and human health implications of nanotechnology in 2006. EPA will manage peer review of the proposals, and all four agencies will select from among those that pass review for funding based on agency relevancy and interest. A similar collaboration among EPA, NSF, and NIOSH in 2005 led to about $7 million in funding for research on the same topic.
- The Nanotechnology Characterization Laboratory (NCL) is supported by a partnership among the National Cancer Institute, NIST, and the FDA. The NCL, which was established in 2005, provides critical expertise and infrastructure for developing and performing safety tests in order to expedite the use of nanomaterials for the diagnosis and treatment of cancer. The expertise of all three agencies is vital to the successful operation of the Laboratory.
- The National Toxicology Program (NTP) is an ongoing partnership among NIH's National Institute of Environmental Health Science (NIEHS), FDA's Center for Toxicological Research, and CDC's NIOSH. Beginning in 2004, the NTP initiated a series of toxicity studies on classes of nanomaterials that are especially promising in a range of applications—carbon "buckyballs" and carbon nanotubes, nanoscale powders of metal oxides, and semiconductor "quantum dots." The early results of these studies are expected in the coming year.

I also want to highlight the research program established in the past two years by NIOSH. As discussed above, while free engineered nanoparticles are not found in most nanotechnology-based products, workplace exposure during manufacture may be cause for some concern. Accordingly, NIOSH has launched an aggressive research program to assess potential toxicity of nanomaterials found in the workplace, and has produced a preliminary document recommending best practices for safe handling of nanomaterials in the workplace. Information on these and other NIOSH activities with respect to nanotechnology are posted on the NIOSH website *(http://www.cdc.gov/niosh/topics/nanotech/)*.

In addition to the various activities within and among the participating federal agencies, the NNI participates in a number of bodies on the international level. Such activities will help to promote responsible development of nanotechnology worldwide.

Organization for Economic Cooperation and Development (OECD): Within the OECD Environmental Directorate, the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology hold regular joint meetings. The next such meeting will be hosted by the United States in the Washington area on December 7–9 and will take the form of a workshop on the safety of manufactured nanomaterials. The objectives of the workshop are to determine the state of the art regarding safety assessment of manufactured nanomaterials and to identify future needs for risk assessment within a regulatory context. The resulting report is expected to discuss issues including nomenclature, human health, environmental hazards, exposure assessment, and possible regulatory frameworks.

International Life Sciences Institute (ILSI): Representatives from EPA and NIOSH participated in a working group convened by the ILSI Research Foundation Risk Sciences Institute to develop a screening strategy for identifying hazards of engineered nanomaterials. The group recently reported on the elements of such a strategy, and recommended broad data gathering. The report acknowledges that at this early stage, there are insufficient data to support a specific testing protocol.

The International Dialogue on Responsible Research and Development of Nanotechnology: The first Dialogue, sponsored by NSF, was held in June 2004 in

Alexandria, Virginia, and brought together 25 countries and the European Commission (EC) to discuss environmental, health and safety issues as well as ethical, legal and other social issues. A follow-up meeting was hosted by the EC in Brussels last July, and a next meeting is planned in Summer of 2006 to be hosted by Japan.

International Standardization Organization (ISO) and American National Standards Institute (ANSI): A critical aspect of protecting health and the environment and a basis of any regulation of chemicals and materials are standardized tools and methods for measuring and monitoring exposure. Research related to measurement science and technology is led by NIST. However, standards are developed jointly by all stakeholders through consensus-based processes. In June 2004, in response to a letter from Dr. John Marburger, Director of the Office of Science and Technology Policy, the American National Standards Institute (ANSI) established a Nanotechnology Standards Panel to facilitate and coordinate nanotechnology standards development in the United States. The NSET Subcommittee and the relevant agencies are members of the Panel and its Steering Committee, and are providing financial support to facilitate its activities.

Subsequently, the International Organization for Standardization (ISO) has established a Nanotechnologies Technical Committee, which held its first meeting last week. As Chair of the ANSI-accredited Technical Advisory Group (TAG) to the ISO and leader of the U.S. delegation, I am pleased to report that the United States will lead the Working Group on Health, Safety, and Environmental Aspects of Nanotechnologies. Our first action will be to submit the NIOSH document on "Approaches to Safe Nanotechnology" to the ANSI TAG as a possible work item for the ISO Working Group. If approved the document will be put forth to the ISO Working Group as a draft to be further developed with inputs from other ISO Technical Committee member countries. Once developed and approved by the Technical Committee, the document will be issued as an international Publicly Available Specification; an informational document available to all countries.

The ISO Technical Committee's granting of leadership in the area of environmental and safety aspects of nanotechnology to the United States is an acknowledgement that we are at the forefront in this area.

NNI-supported studies are providing useful preliminary information, but more research is needed.

Preliminary research to date shows, not surprisingly, that not all nanomaterials are alike. Earlier this month, researchers at Rice University released results showing that the toxicity of carbon nanotubes can be reduced by engineering of the nanotube surface, as they had shown earlier for buckyballs. Such data indicate that, unlike naturally occurring or incidental nanoparticles, engineered nanomaterials may be tailored to reduce toxicity.

In another study published recently in the journal *Pharmaceutical Research,* a group headed by Dr. Russell Mumper at the University of Kentucky, tested nanoparticles coated with polyethylene glycol (PEG), a polymer used to protect many types of therapeutic agents from elimination by the immune system. The investigators developed a test to determine how PEG-coated nanoparticles affected a variety of *in vitro* and *in vivo* parameters, including blood clotting time, red blood cell damage, and platelet aggregation or clumping. They found that a concentration of nanoparticles one might expect in the blood stream produced no untoward biological effects on blood cells.

These two studies are only a sampling of the wide range of work underway within the NNI. While time does not permit me to describe the work taking place across all of the agencies that support research on environmental and safety implications of nanotechnology, I encourage you to see the NNI FY 2006 Supplement to the President's Budget and the NNI website, *www.nano.gov,* for additional detail.

Current research is providing data that are helping us understand the way nanomaterials interact with biological systems and the environment. However, substantial work remains, including in the following areas.

- Methods and metrics for determining nanoparticle exposure and dose received among workers, consumers, and the environment, as well as fate and transport once the dose is received.
- Methods for controlling exposure in the workplace, including monitoring and personal protective equipment.
- Analytical methods for characterizing nanomaterials properties and behavior. Most toxicologists and the general research community agree that new toxicity tests/methods are not needed for nanomaterials. What is needed is the application of novel (to toxicologists) physical/chemical characterization and

detection methods so that researchers can be assured the materials being studied have the expected and desired properties. The unfortunate fact that so many toxicology papers on nanomaterials are difficult to interpret is not because the toxicology study protocols are not up to the task, it's because the reporting of the characterization of the materials is inadequate.

- Experimental and computational approaches to determine biological effects, including toxicity.
- Methods for assessing and managing risk of nanomaterials.

The research needed in this area will be addressed by the various stakeholders, including not only the Federal Government, but also industry and research institutions. The Federal Government will play an important role through its broad support of research, including basic research on the environmental and health effects of nanomaterials. The Government supports research aimed at understanding nanomaterials and how they interact with cells, organisms, and the environment. The Government also supports research aimed at developing tools and methods for measuring and assessing nanomaterials. Such research expands knowledge and understanding, and supports the Federal Government's regulatory role by enabling science-based decision-making.

Yet, we know that much more needs to be done, and many questions remain unanswered. We should not expect that we will have all of the answers quickly. Research takes time, especially on a subject this complex. We already know that all nanomaterials are not created equal in terms of potential hazard or potential exposure. A carefully designed research plan, along with shared Government and industry responsibility and collaboration should guide our efforts. We must evaluate research results carefully, and if we discover that there are dangers associated with certain materials in specific uses, we should determine what restrictions might be necessary, including applying current regulatory authorities. Above all we need to be guided by science, not by irrationality or emotion. Finally, we need to communicate effectively and openly with the public. Nothing else will establish trust and credibility.

Thank you for the opportunity to speak today on this important aspect of nanotechnology.

BIOGRAPHY FOR E. CLAYTON TEAGUE

Clayton Teague has served as Director of the U.S. National Nanotechnology Coordination Office (NNCO) since April 2003. Dr. Teague is on assignment from the National Institute of Standards and Technology (NIST), where he is Chief of the Manufacturing Metrology Division in the Manufacturing Engineering Laboratory.

Dr. Teague has worked in the field now known as nanotechnology for most of his professional career, beginning with his metal-vacuum-metal tunneling experiments in the 1970's. He continued to work with such precision instrumentation as scanning tunneling microscopes, atomic force microscopes, displacement and phase-measuring interferometers, stylus instruments, flexure stages, and light scattering apparatus, which he utilized for ultra-high accuracy dimensional metrology of surfaces on micrometer to nanometer-scales.

Dr. Teague is a member and two-times Past President of the American Society for Precision Engineering, and a fellow of the UK Institute of Physics. He served as Editor-in-Chief of the international journal *Nanotechnology* for ten years and remains a member of its Editorial Board. He holds a B.S. and M.S. in physics from the Georgia Institute of Technology and a Ph.D. in physics from the University of North Texas. He has authored or co-authored over 70 papers, has presented 50 invited talks in the technical fields described, and jointly with colleagues, has six patents.

Dr. Teague's work has been recognized with the Gold Medal, Silver Medal, and Allen V. Austin Measurement Science Award from the Department of Commerce, the Kilby International Award from the Kilby Awards Foundation, and an IR–100 Industrial Research and Development Award. He is the 2004 winner of a Best of Small Tech Awards for Advocacy from *Small Times Magazine.*

Chairman BOEHLERT. Thank you, Dr. Teague. Mr. Nordan.

STATEMENT OF MR. MATTHEW M. NORDAN, VICE PRESIDENT OF RESEARCH, LUX RESEARCH, INC.

Mr. NORDAN. Good morning, Chairman Boehlert, Ranking Member Gordon, and Members of the Committee, and thank you for inviting me to testify today.

My company, Lux Research, advises corporations, investors, startups, and public sector institutions on exploiting nanotechnology for competitive advantage, and each of these groups shares an interest in today's topic: the environmental, health, and safety, or EHS risks of nanotechnology.

The United States needs nanotechnology applications to solve critical problems, like treating chronic disease, and developing new energy sources, as well as to sustain the technology-based economic development that has driven the U.S. economy since World War II. We project that in 2014, about one sixth of manufacturing output will incorporate emerging nanotechnology in some way. The U.S. cannot be left behind in this field.

However, we must also ensure that these applications are developed responsibly, without compromising the health of citizens or the environment. Now, decades of lessons learned from coping with new materials have given businesses well-established risk analysis frameworks that can be applied to nanotechnology, but only if two key requirements are met. First, businesses need a solid base of data about nanoparticle toxicology. Second, they need clarity about how agencies like the EPA and the Consumer Product Safety Commission will approach regulation. Today, both of those requirements are absent, and this is slowing nanotech commercialization in the U.S. Many corporate executives and venture capitalists that we have spoken with have told us that they are limiting their nanotechnology programs until they can address EHS risks with more confidence.

There are two distinct classes of risk to address. On one hand, there are real risks. The fact that some of the many diverse types of nanoparticles could be found to be harmful in real world usage scenarios. But on the other hand, there are perceptual risks. Even if every type of nanoparticles turned out to be harmless, public skepticism could still sharply limit the use of nanoparticles in products, similar to the situation that Mr. Gordon presented with genetically modified organisms in Europe. Either class of risk could prevent the U.S. from reaping the full benefits of nanotechnology.

We believe that the Federal Government can take three key actions to address both real and perceptual risks, and ensure responsible development of nanotech applications. First, the government can wield its influence to unify splintered toxicology efforts. There are many initiatives worldwide that address nanoparticles toxicology, and they are highly uncoordinated. As a result, they waste scarce resources available to investigate real risks, and they also ignite a known fear factor for perceptual risks.

A globally recognized body of record is needed. Because the public will justifiably be skeptical of any industry-convened authority, we feel that this body must reside in the public sector. We recommend that the U.S. National Science Foundation, the European Commission's Nanosciences and Nanotechnologies Unit, and Japan's Ministry of Economy, Trade, and Industry establish an Inter-

national Nanoparticle Toxicology Authority to unite today's splintered efforts.

Now, second, the government can fund nanoparticles toxicology research. Large corporations like DuPont have the resources and incentives to fund such studies on their own, but the hundreds of startups that are active in the field do not. The only way that we see for nanotech commercialization to proceed rapidly through these companies, while ensuring that toxicology studies are performed, is for government to supply the funds. Now, currently, not enough money is available. Only 3.7 percent of the $1.05 billion U.S. NNI budget for 2006 is earmarked for research on EHS issues.

We recommend that the Federal Government establish a National Nanotechnology Toxicology Initiative to address these issues. With an annual budget geared like an insurance policy of sorts for nanotech development, the annual funding required likely lies between $100 million and $200 million per year, two to four times today's spending. To ensure commercial relevance, the initiative should allocate research funding through a market-based mechanism. Such a mechanism would require companies to submit their materials for testing, as a condition of receiving government research grants.

Finally, government can eliminate regulatory ambiguity for industry. No regulatory agency that we are aware of has articulated a clear and unambiguous plan for how it will approach nanotechnology. The EPA serves as a telling case. It is relying on a working group to suggest voluntary guidelines that has taken a long time to come to decisions. We feel that these dynamics will neither provide regulatory clarity nor do so in a timely manner. This regulatory clarity is needed both to address real risks, but also perceptual ones. Nongovernmental organizations that have called for outright bans on nanotech R&D have cited absent regulation as their key concern.

We recommend that the EPA, as well other agencies exposed to these issues, including the FDA, NIOSH, and the CPSC, establish and communicate clear plans for resolving regulatory ambiguity. These plans should describe the potential range of outcomes, the questions that will lead to choosing one outcome over another, the process for answering those questions, and closed-ended timeframes for completion. We recommend completion dates no later than the end of 2006.

Asbestos was mined by the ton for 30 years before lab research showed it to be harmful. In contrast, nanoparticles toxicity experiments are being conducted proactively today, in parallel with development of the materials themselves. Because of this, I am confident that nanotech EHS issues will be addressed responsibly, if they see wise action by government.

Thank you again for inviting me to speak, and I am pleased to answer any questions.

[The prepared statement of Mr. Nordan follows:]

PREPARED STATEMENT OF MATTHEW M. NORDAN

Nanotech Environmental, Health, and Safety (EHS) Risks: Action Needed

The U.S. must cultivate nanotechnology applications to solve pressing strategic problems and drive economic growth, but must also ensure that the health and safety of its citizens are not compromised. Established frameworks for assessing EHS risks can be applied to nanotech, but not enough hard data about the hazard and likely exposure of nanoparticles exists to make firm determinations. The U.S. Government can speed responsible development by uniting splintered nanoparticle toxicology efforts, funding core toxicology research at two to four times today's level, and eliminating regulatory ambiguity for industry.

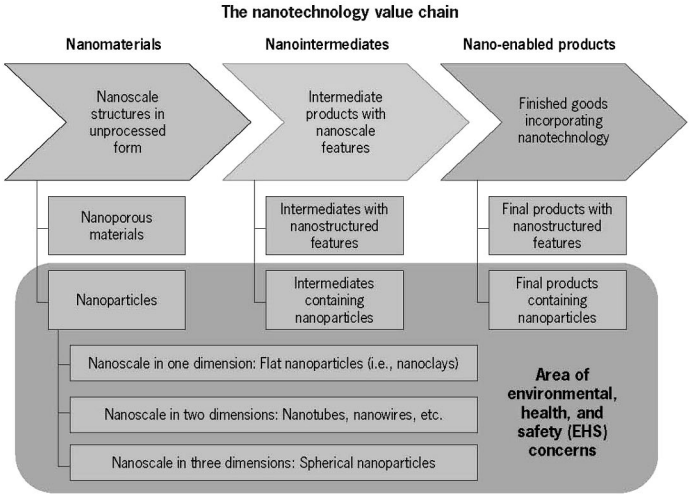
EHS Issues Are the Wildcard in Nanotech Development

The U.S. needs nanotechnology applications to solve critical problems in fields including energy generation, electricity distribution, treatment of chronic diseases like cancer and Alzheimer's, and environmental remediation—as well as to sustain the technology-based innovation that drives the U.S. economy. The U.S. Government has responded admirably to this challenge by delivering ample funding for nanotech research through the National Science Foundation, the Department of Defense, the National Institutes of Health, and other agencies—as well as a culture of support for the commercialization of this research through vehicles like Small Business Innovation Research (SBIR) grants, which help start-up companies turn nanotech innovations into products.

However, the U.S, *also* needs nanotech applications to be developed responsibly, ensuring the health and safety of citizens in both the short- and long-term. As awareness of nanotechnology has grown, so has concern over its environmental, health, and safety (EHS) risks—the prospect that nano-enabled products might harm workers, consumers, or ecosystems. The debate concentrates on nanoparticles: bits of matter with sub-100 nm dimensions which may either be miniature chunks of established materials (like Nanophase's nanoscale zinc oxide, used in sunscreens), or highly ordered structures that only form at the nanoscale (like CarboLex's single-walled carbon nanotubes, which may be soon used in flat-panel displays) (see Figure 1).[1]

[1] For a more detailed discussion of the nanotechnology EHS debate, see the May 2005 Lux Research report "A Prudent Approach to Nanotech Environmental, Health, and Safety Risks."

Fig. 1: Nanotech EHS Concerns Focus on Nanoparticles and the Products that Incorporate Them



Concerns arise over these engineered nanoparticles for three reasons: 1) they are known to have unique physical, chemical and biological properties; 2) "incidental nanoparticles" with similar dimensions, formed unintentionally through processes like welding and diesel combustion, are already known to be harmful if inhaled, swallowed, or absorbed through the skin; and 3) early studies have shown cause for concern over some types of engineered nanoparticles. Many parties are involved in nanotech EHS debate, including corporate EHS officers, start-ups, non-governmental organizations (NGOs), regulatory agencies, insurers, toxicology researchers, journalists, and consumers (see Figure 2).

Two Distinct, Equally Important Classes of Risk Impact Nanotech

Two distinct classes of EHS risks will impact whether nanotechnology applications will generate economic growth and improve quality of life—or be abandoned:

- **Real risks.** As toxicity and exposure data on nanoparticles builds, one, many, or all types could indeed be found harmful to people or to the environment. If many or most types of nanoparticle proved hazardous, nanotech commercialization would rightfully slow down or stop.

Fig. 2: Many Parties Are Involved in the Nanotech EHS Debate

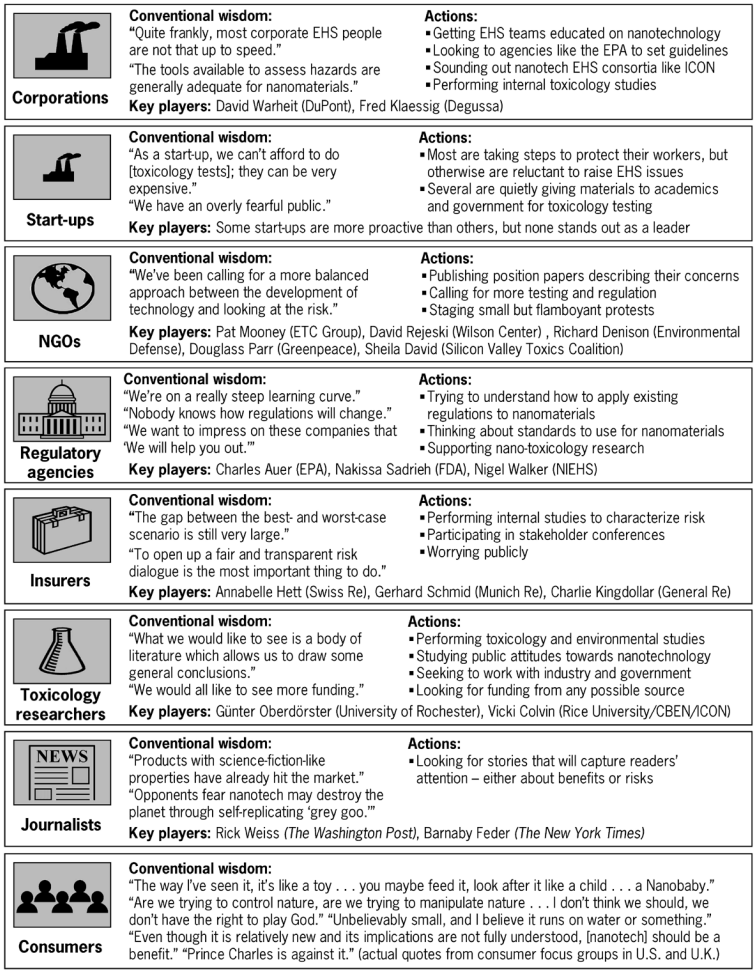
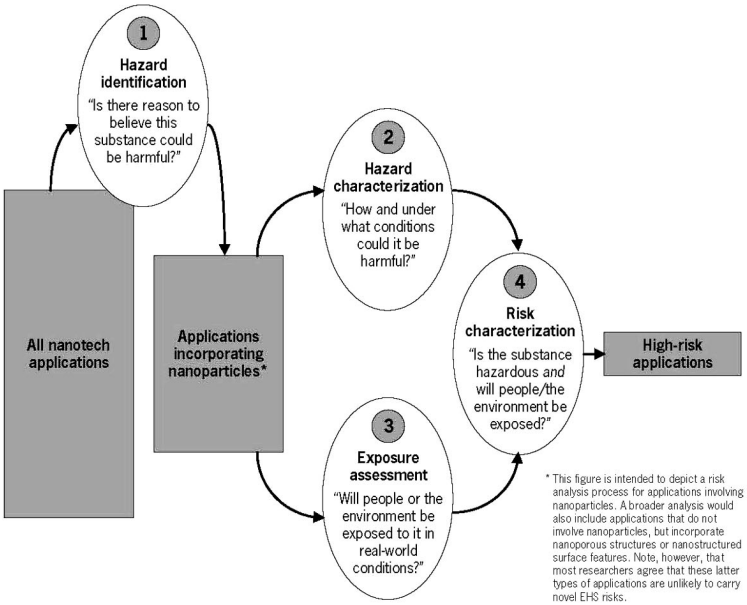


Fig. 3: Applying Established Risk Analysis Methods to Nanotechnology



- **Perceptual risks.** Even if studies showed every commercially relevant nanoparticle to be harmless in every real-world usage scenario, public skepticism about the safety of nanoparticles could still build and sharply limit the use of nanoparticles in products—similar to the situation encountered with genetically modified organisms (GMOs) in Europe.

Responsible development of nanotechnology—to ensure that the U.S. obtains the full benefits of nanotechnology applications—requires addressing both real and perceptual risks.

The Good News on Real Risks: Established Frameworks Exist to Assess Threats

Because engineered nanoparticles are both new and highly diverse, there's a widespread perception that no acceptable methods exist for assessing their EHS risks. This isn't true. Decades of lessons learned from coping with new materials from polymers to DDT have yielded well-established risk analysis frameworks, which can be applied to nanotechnology in a straightforward fashion. They generally employ four steps (see Figure 3):

- **Step one: Identify hazard.** This step answers the question "Is there reason to believe this substance could be harmful to people or the environment?" Many nanotech applications do not involve any nanoparticles at all; they employ bulk structures that have nanoscale features, which are unlikely to pose a novel toxicology risk. Such applications include nanolithography used to pattern ever-smaller features on microchips, nanoscale layers of magnetic material used to make new forms of memory chips, and nanoporous materials used for insulation. Identifying these applications that are very unlikely to be hazardous underscores the point that "nanotechnology does not equal nanoparticles" and effectively bounds the risk assessment domain.
- **Step two: Characterize hazard.** This step answers the question "How and under what conditions could the substance be harmful?" There is no one-size-fits-all answer for "nanoparticles" as a group; answers will differ for the many different types of nanoparticles that have been developed, which range from those likely to be benign (e.g., nanoclay particles) to those deserving of great-

er scrutiny (e.g., fullerenes and single-walled carbon nanotubes). Even for a single type of nanoparticle, the level of hazard will vary by dose (even water is toxic when massively ingested) and route of administration (i.e., ingestion versus skin contact).

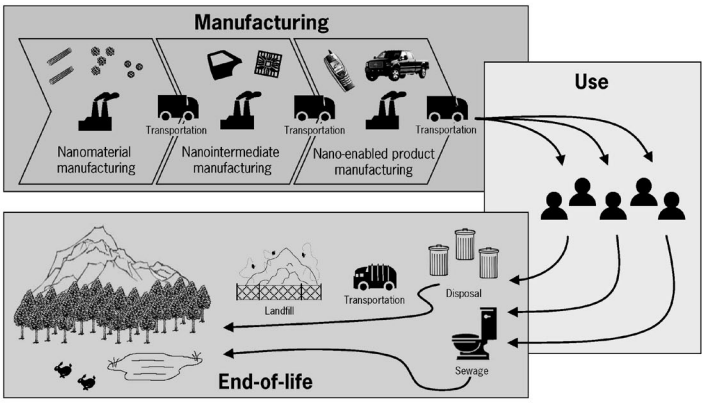
- **Step three: Assess exposure.** This step answers the question "How will people and the environment come into contact with this substance?" Exposure assessment must factor in real world conditions: Kitchen cabinets are full of cleaning supplies that are deadly, but only if someone drinks them. It's also important to note that most applications of nanoparticles deploy the particles in a *fixed* form in which they cannot enter the body, because they are (for example) cross-linked in a plastic resin or covalently bonded to a semiconductor substrate. Relatively few applications deploy nanoparticles in a *free* form—in air or liquids—in which they could be inhaled, be ingested, or penetrate the skin.

  The potential for exposure to nanoparticles used in a product will vary over that product's life cycle, which can be broken down into three key stages (see Figure 4). First, in *manufacturing,* workers can be exposed to free nanoparticles at higher levels that at any other point of the life cycle, but the risks are the most straightforward to address because manufacturing lines are tightly controlled—many businesses already cope successfully with highly toxic substances. Secondly, consumers may be exposed during use, either deliberately (as in food, cosmetics, and pharmaceutical applications) or unintentionally. Finally, at *end-of-life,* the environment and ultimately the general population may be at risk when products containing nanoparticles are disposed of; here we see the most unanswered questions because little research has been conducted and experiments are difficult to design.

- **Step four: Characterize risk.** Only when the first three steps have been completed can one make meaningful judgments about the EHS risks of a specific nanotechnology application. To conclude high risk, a hazard must exist that either workers, consumers, or the environment is significantly exposed to in real-world conditions.

Based on our ongoing research on the commercialization of nanoparticles, we believe that these high-risk cases will be rare because the overwhelming majority of applications deploy nanoparticles in fixed form, in very small amounts, or both. With that said, action is required to identify high-risk applications, to ensure the safety of workers in manufacturing plants that make products based on any type of nanoparticle, and to gain insight into the EHS issues of nanoparticles at end-of-life.

Fig. 4: Potential for Exposure to Nanoparticles Varies Across the Product Life Cycle

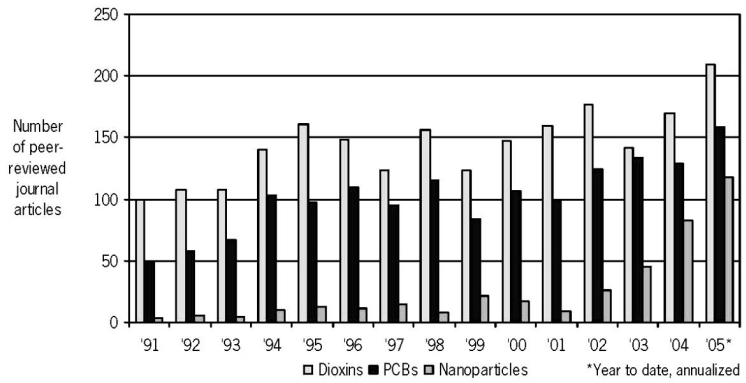


Factor	Manufacturing	Use	End-of-life
Degree of system control	High	Medium	Low
Time from exposure to impact	Short to long	Long	Long
Primarily at risk	Workers	Consumers	Environment
Key form of potential nanoparticle exposure	Free nanoparticles	Fixed nanoparticles	Fixed nanoparticles
Degree of regulation at life cycle stage	High	Medium	Low
Incentives by producers to invest in countermeasures	High	High	Medium
Number of individuals potentially at risk	Tens to thousands	Thousands to millions	Millions to billions
Opportunity for exposure to large volumes	Frequent	Rare	Possible over time
Unresolved questions	Few	Some	Many

The Bad News on Real Risks: Scarce Hard Data Means Firms Struggle to Apply Known Frameworks

If well-established frameworks exist to assess the EHS risks of nanoparticles, why is there a debate? To apply these frameworks, researchers and start-ups require hard data about hazard and exposure. The nanotech EHS debate comes down to an absence of this data.

Fig. 5: Journal Articles on Toxicity for Nanoparticles versus Dioxins and PCBs



Large corporations like DuPont and start-up companies like Nanotechnologies Inc. must make decisions *now* about which nanotechnology applications to invest in: They're under pressure from shareholders to innovate and don't want competitors to beat them to potentially valuable new products. But when they attempt to apply established risk assessment frameworks to make wise decisions—and decide which applications to pursue for regulatory approval—they face:

- **Data that's insufficient to draw conclusions, but sufficient to cause concern.** A search on the Science Citation Index as of May 21, 2005 for peer-reviewed articles about toxicity since 1991 revealed only 503 citations for nanoparticles, compared with 2,046 and 1,437 citations respectively for two more conventional (and much narrower) classes of toxins: polychlorinated biphenyls (PCBs) and dioxins (see Figure 5).[2] Of nanoparticle studies that do exist, many raise cause for concern: Widely-cited work by Eva Oberdörster of Southern Methodist University found that fullerenes damaged the brains of largemouth bass at concentrations of only 0.5 parts per million.[3] Others, however, contradict these findings. Grigoriy Andrievsky of the Ukrainian Academy of Medical Sciences claimed that Oberdorster's effects were due wholly to the solvents she used, not the fullerenes themselves.[4]

  Nanoparticle toxicity will vary widely depending on how nanoparticles enter the body, in what quantities, and how they're dispersed, coated, and functionalized. As a result, it's clear that far more research is required to definitively assess the toxicity of a meaningful range of nanoparticle types in real-world usage scenarios. To date, even conducting measurements has been difficult because of a lack of instrumentation and metrics to quantify nanoparticle concentration and mobility. For example, academic studies suggest that for nanoparticles, total surface area rather than total mass is most important in assessing risk—but the pioneering work at the U.S. National Institute for Occupational Safety and Health (NIOSH) on constructing devices to measure the surface area of nanoparticles in the air remains at an early stage.

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[2] Source: Science Citation Index as of May 21, 2005; search terms "(toxici* OR toxico*) AND (X)," where X = "dioxin*," "PCB,*" or "(quantum dot OR nanopartic* OR nanotub* OR fulleren* OR nanomaterial* OR nanofib* OR nanotech* OR nanocryst* OR nanocomposit*)."

[3] Source: "Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass," Oberdörster, *E. Environ. Health Perspect.* 2004, 112, 1058–1062.

[4] Source: "Is a Fullerene C60 Molecule Toxic?" Andrievsky, G.; Klochkov, V.; Derevyanchenko, L. Institute for Therapy of Ukrainian Academy of Medical Sciences, 2004, open letter (contact GVAndrievsky@yahoo.com).

Fig. 6: A Sample of Regulatory Regimes that Address Nanotech Applications Highlights Confusion

U.S.				
Agency	**Regulation**	**What it covers**	**Nanotech activity**	**Contact(s)**
EPA	Toxic Substances Control Act (TSCA)	Requires registration and testing of new materials	Not yet clear if nanoscale versions of previously tested materials will need to be re-registered as new substances; developing volutary pilot program	Charlie Auer, Flora Chow
FDA	Federal Food, Drug, and Cosmetic Act	Products that make health claims need to be evaluated; otherwise, the FDA will only intervene if complaints arise	Eager to work with companies to understand the effects of nanomaterials and to assist with approval processes	Nakissa Sadrieh
OSHA	Occupational Safety and Health Act of 1970	Any risks to workers from nanomaterials would fall under OSHA's purview	Actively studying effects of nanoparticles through National Institute for Occupational Safety and Health (NIOSH) in order to develop workplace standards	Vincent Castranova (NIOSH)
NIEHS	National Toxicology Program	Coordination of toxicology studies on materials of concern	Nanomaterials as a class were nominated for testing by Vicki Colvin of Rice in 2003	Nigel Walker
Europe				
Entity	**Authority**	**What it covers**	**Nanotech activity**	**Contact(s)**
U.K.	Health & Safety Executive	Covers all risks to health and safety arising from work	Very proactive at looking into nanotech risks; has published guidance for companies on its Web site at www.hse.gov.uk	Christine Northage
EU	Registration, Evaluation, and Authorization of Chemicals (REACH)	Still under discussion, but will eventually require registration and evaluation of chemicals across all EU member states	As with TSCA in the US, the status of nanomaterials under REACH has not been determined	Renzo Tomellini

- **Regulatory regimes in flux.** The question of "which regulatory regime covers a given nanoparticle application today?" often can't be answered (see Figure 6). For example, the EPA's Toxic Substances Control Act (TSCA) requires new chemicals to be submitted for testing before being sold, but do carbon nanotubes count as a "new chemical" or simply a form of previously-approved carbon?[5] The answers to these questions will be determined by the working groups that organizations like the EPA, the FDA, and NIOSH have only recently formed. The outcome of these debates can't be reliably predicted because proposed solutions vary widely, from voluntary reporting of toxicity data to mandatory labels that might accompany products containing nanoparticles.[6]

These two issues—absent data and regulatory ambiguity—are slowing nanotechnology commercialization in the U.S. today. Many corporate executives and venture capitalists have told us that they are scaling back their nanotechnology programs until they can address EHS issues with more confidence. In other countries where EHS issues are not prioritized as highly as in the U.S., nanotechnology applications have come to market much more quickly: For example, no major U.S.-based coatings company has introduced a broad line of paints incorporating nanoparticles for anti-microbial, anti-UV, or self-cleaning effects, but such products are widespread in China and other east Asian countries.

To be clear, Lux Research does *not* advocate any departure from rigorous testing and regulatory procedures in order to speed products to market that incorporate nanotechnology. Many past well-intentioned technologies with unanticipated ill effects, such as asbestos, show that such a decision would be monumentally unwise for citizens and the economy. Instead, we recommend that the federal government use its resources and influence to 1) build the base of data required to conduct rigorous risk assessment of nanoparticle applications, and 2) promptly eliminate ambiguity about which regulatory procedures apply.

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[5] For more information on TSCA's applicability to nanomaterials, see the February 14, 2005 Lux Research flash "Nanotech Health and Safety Regulation: It's Already Here, with More on the Way."

[6] Reports from insurer Swiss Re, the U.K.'s Royal Society, and the European Commission's Community Health and Consumer Protection Directorate General have all stated that there is a case for mandatory labeling of products that incorporate nanoparticles.

Nanotech Looks Primed for Perceptual Risk

What about perceptual risk? We suggest that U.S. corporations and start-ups developing nanotechnology applications have as much to lose from perceptual risk as from real ones. Real risks apply to specific materials and applications that can be individually addressed, but perceptual risk could make commercialization of *any* nanomaterial infeasible. Sociological research has identified reliable attributes of new technologies that trigger consumer concern, described in models with names like "fright factors" and "principal outrage components." When rated against these factors, nanotech scores poorly—for example, when lined up against the eleven "fright factors" documented by Peter Bennett of the U.K. Department of Health, nanotech rates well on only one and poorly on six (see Figure 7).

Fig. 7: Nanotech Exhibits Many "Fright Factors" that Set Off Perceptual Risk

Fright factor[a]	Likely perception of nanotech by consumers	Comments
Involuntary	Negative	Consumers are likely to use products containing nanomaterials without knowing it
Inequitably distributed	Neutral	In some cases individuals may be exposed to nanoparticles without experiencing the benefits of their use
Unavoidable by taking personal precautions	Neutral	Some precautions can be taken to avoid exposure, but they are unlikely to be well-understood or trusted
Arises from unfamiliar or novel sources	Negative	Nanotechnology is certainly novel and remains mysterious to most of the public
Results from man-made sources	Negative	Engineered nanoparticles by definition don't exist in nature
Causes hidden and irreversible damage	Negative	Nanoparticles could accumulate in the body or environment unbeknownst to consumers, leading to chronic effects
Poses particular danger to the vulnerable (e.g., children, the elderly)	Positive	While specific applications may differ, in most cases these populations will not be at greater risk
Threatens death, illness, or injury arousing particular dread	Neutral	No "nuclear threat" exists, but the possibility that exposure to nanoparticles could causes cancers or other conditions does
Damages identifiable rather than anonymous victims	Neutral	Consumers would likely be anonymous, but factory exposure would affect specific individuals and likely be widely publicized
Poorly understood by science or responsible agencies	Negative	Both researchers and regulators are plainly struggling to understand the possible effects of nanoparticles
Described in contradictory statements from responsible sources	Negative	Consumers are confronted with both wildly utopian and wildly apocalyptic visions of nanotech's effects

a. Bennett, P.; Calman, K. *Risk Communication and Public Health.* Oxford University Press, Oxford, 1999.

Despite the potential for perceptual risk, consumer perceptions of nanotechnology have not yet been set: Surveys of consumers in both the U.S. and Europe have universally found very low overall awareness of nanotechnology (see Figure 8). Given this, it's astonishing that both corporations and start-up companies active in nanotech have done almost nothing to date to engage consumers on the topic. We have recommended to corporations and start-ups that the best approach to heading off perceptual risks involves engaging consumers honestly about nanotechnology applications by articulating nanotech benefits, communicating toxicology efforts, and working cooperatively with NGOs and other stakeholders, as DuPont has done by partnering with Environmental Defense.

How the U.S. Government Can Help Address both Real and Perceptual Risks

Based on our research, we believe that the U.S. Government can help industry to develop nanotechnology applications responsibly and help consumers to make informed judgments about the benefits and risks of products incorporating nanotech. To do so, we feel the government should:

- **Wield influence to unite splintered toxicology research efforts.** Many different initiatives to address nanotech EHS risks exist—from government-sponsored efforts like the EU's Nanosafe2 initiative, to corporate/university hybrids like the International Council on Nanotechnology (ICON), to programs at professional societies like the American Chemistry Council. To the

extent that these initiatives replicate the same work, they waste scarce resources available to investigate real risks. To the extent that they send conflicting messages to the public, they ignite a well-known "fright factor" for perceptual risk.

To move nanotech EHS research forward, a clearly identified body of record is needed to coordinate these splintered efforts. For the sake of addressing perceptual risk, we believe a government-backed entity will be superior to any industry-backed one, which will almost certainly be perceived as having conflicted incentives. We recommend that the U.S. National Science Foundation, the European Commission's Nanosciences and Nanotechnologies Unit, and Japan's Ministry of Economy, Trade, and Industry join forces to establish an International Nanoparticle Toxicology Authority (INTA) to form a coordinating interface for today's splintered efforts.

Fig. 8: Consumers Are Still Largely Unaware of Nanotech, but Generally Respond Positively

Researcher(s)	Year	Description	People	Region	Awareness	Attitude	Key finding
Bainbridge[a]	2001	Web-based survey	3,903	U.S.	n/a	👍	58% agreed humans would benefit greatly from nanotech
Gaskell, Allum & Stares[b]	2002	Face-to-face survey	15,000	Europe	n/a	🤷	29% felt nanotech would improve life, 53% didn't know
Gaskell, Ten Eyck, Jackson & Veltri[c]	2002 to 2003	Telephone survey	850	U.S.	n/a	👍	50% felt nanotech would improve life, 35% didn't know
BMRB Social Research[d]	2004	Face-to-face survey	1,005	U.K.	Low	👍	Of those who could define it, 68% thought it would improve life
Cobb & Macoubrie[e]	2004	Telephone survey	1,536	U.S.	Low	👍	78% thought benefits would outweigh or be equal to risks
Macoubrie[f]	2004	Face-to-face focus groups	152	U.S.	Low	👍	After descriptions, 80% thought benefits would outweigh risks
Currall et al.[g]	2004	Web-based survey	4,543	U.S.	n/a	👍	Average respondent was "quite positive" on a scale of 1 (extremely negative) to 6 (extremely positive)

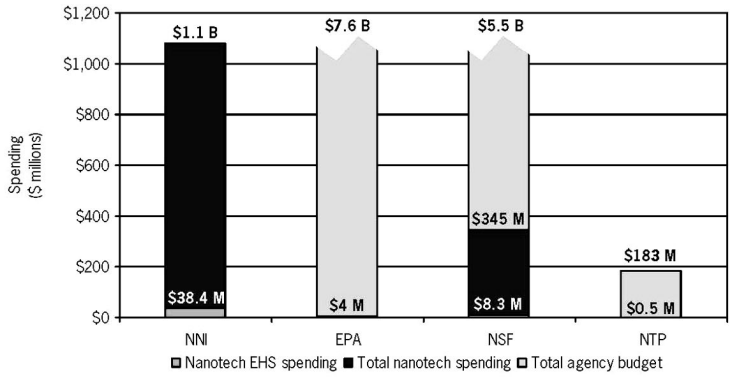
a. "Public attitudes toward nanotechnology." Bainbridge, W.S. *J. Nanoparticle Res.* **2002**, *4*, 561-570.
b. Gaskell, G.; Allum, N.; Stares, S. *Europeans and Biotechnology in 2002: Eurobarometer 58.0*; Methodology Institute, London School of Economics: London, U.K., 2003.
c. "Imagining nanotechnology: cultural support for technological innovation in Europe and the United States." Gaskell, G; Ten Eyck, T.; Jackson, J.; Veltri, G. *Public Understand. Sci.* **2005**, *14*, 81–90.
d. BMRB. *Nanotechnology: Views of the General Public;* BMRB International: London, U.K., 2004. (available at www.nanotec.org.uk)
e. "Public perceptions about nanotechnology: Risks, benefits and trust." Cobb, M.D.; Macoubrie, *J. J. Nanoparticle Res.* **2004**, *6*, 395-405.
f. Macoubrie, J., personal communication. Manuscript in preparation, North Carolina State University.
g. Currall, S.C., personal communication. Manuscript in preparation, Rice University.

- **Accept that the government must ultimately fund fundamental toxicology research on nanoparticles—and allocate funding through a market-based mechanism.** Large corporations have a keen interest in performing toxicology research on nanoparticles because their time horizons are long enough to incorporate negative outcomes that take decades to appear—and because institutional shareholders with long positions, like pension funds, hold them accountable. Start-ups, on the other hand, have much shorter time horizons, and thus face financial incentives to bury or disregard EHS issues if they threaten to compromise the company's near-term valuation or likelihood of an exit. Regulation must intervene to align startups' inherently short-term interests with long-term public good.

  Start-ups are generally the earliest commercial developers of new nanoparticles and also the parties least likely to be able to afford expensive toxicology studies. As long as these dynamics hold, the only way we see for nanotech commercialization to proceed rapidly while ensuring that toxicology studies are performed is for governments to supply the funds. Currently, however, not enough money is available to fund the necessary research. Only 3.7 percent of the $1.05 billion U.S. National Nanotechnology Initiative (NNI) budget for 2006 is earmarked for research on EHS issues, and spending on

nanoparticle research at other relevant government agencies remains low (see Figure 9).

Fig. 9: U.S. Government Funding for Nanoparticle Toxicity Research



NNI = National Nanotechnology Initiative, projected for FY2006
EPA = Environmental Protection Agency, program announced November 12, 2004
NSF = National Science Foundation, funding awarded to date
NTP = National Toxicology Program, currently earmarked for nanomaterial toxicology studies

We believe the U.S. Government should establish a National Nanotechnology Toxicology Initiative (NNTI) to ensure that fundamental nanoparticle toxicology research is performed. With annual budgets geared as an "insurance policy" for nanotech development, the annual funding required in the U.S. likely lies between $100 and $200 million per year—two to four times today's spending. To ensure commercial relevance, the NNTI should allocate research projects through a market-based mechanism based on public nanotechnology R&D funding. This could be linked to SBIR grants: Companies receiving funding for products that incorporate nanoparticles would be obligated to submit their materials for anonymous testing by the NNTI as a condition of the grant. The NNTI would allocate funding for studies of different nanoparticles in proportion to the funding going to their development.

To ensure that the greatest number of studies is performed without allocating resources toward redundant ones, the NNTI should coordinate research in an international network like the one previously suggested. Finally, the NNTI should also emphasize identifying ways to mitigate undesirable effects of nanoparticles, rather than simply identify those effects. Rice University's Center for Biological and Environmental Nanotechnology, which has both identified EHS risks of the fullerene family of nanoparticles *and* identified methods of reducing those risks by functionalizing fullerenes, provides the best model to date.

- **Eliminate regulatory ambiguity for industry.** Many individuals at regulatory agencies in the U.S. are diligently studying nanoparticles, but few agencies have established clear guidelines for how they plan to address them. Most efforts are working groups, like the one currently operating at the Environmental Protection Agency (EPA), which aims to establish voluntary standards in consensus with industry. Such programs take a great deal of time to come to decisions. We believe these time frames must be accelerated, and that more transparency in their decision-making is required.

  Despite natural suspicion to the contrary, most corporations would welcome informed regulation of nanoparticles: "We want to have some certainty, have some clarity, and have a level playing field," one EHS officer from a U.S.-based Fortune 1,000 company told us. Not only does knowing what the future regulatory environment will be allow companies to plan accordingly, but having regulations in place limits the possibility that irresponsible behavior by

a few companies could lead to a public perception disaster for the field of nanotechnology as a whole. In addition, regulatory guidance will help build public trust and confidence in nanotech, inoculating against perceptual risk: Non-governmental organizations that have called for bans on nanotechnology R&D have often cited the absence of regulation as their key concern.

We recommend that the EPA, as well as other agencies exposed to these issues including the FDA, NIOSH, and the Consumer Product Safety Commission (CPSC), establish and communicate clear plans for resolving regulatory ambiguity about applications of nanoparticles. These plans should describe the potential range of outcomes, the questions that will lead to choosing one outcome over another, the process for arriving at answers to those questions, and close-ended timeframes for arriving at them. We recommend setting a hard date no later than the end of 2006 for reaching conclusions on these issues.

BIOGRAPHY FOR MATTHEW M. NORDAN

Matthew Nordan heads Lux's research organization. Under Matthew's leadership, the Lux Research analyst team has become a globally recognized authority on the business and economic impact of nanotechnology. Lux Research serves as an indispensable advisor to corporations, start-ups, financial institutions, and governments seeking to exploit nanotechnology for competitive advantage.

Matthew has counseled decision-makers on emerging technologies for a decade. Prior to Lux Research, Matthew held a variety of senior management positions at emerging technology advisor Forrester Research, where he most recently headed the firm's North American consulting line of business. Earlier, Matthew lived for four years in the Netherlands growing Forrester's operations in Europe, where he launched and led research practices in retail, mobile commerce, and telecommunications.

Matthew has been invited by news outlets including CNN and CNBC to comment on emerging technology markets and has been widely cited in publications such as *The Wall Street Journal* and *The Economist.* He has delivered advice to clients and been an invited speaker at conferences in North America, Europe, Southeast Asia, Japan, Australia, and South Africa. Beyond the corporate sphere, Matthew has participated in developing public-sector technology strategy for organizations including the World Economic Forum, the European IT Observatory, and the Dutch transportation ministry.

Matthew is a summa cum laude graduate of Yale University, where he conducted cognitive neuroscience research on the neural pathways mediating emotion and memory.

November 15, 2005

The Honorable Sherwood Boehlert
Chairman, Science Committee
2320 Rayburn Office Building
Washington, DC 20515

Dear Congressman Boehlert:

Thank you for the invitation to testify before the Committee on Science of the U.S. House of Representatives on November 17th for the hearing entitled "***Environmental and Safety Impacts of Nanotechnology: What Research is Needed?***" In accordance with the Rules Governing Testimony, this letter serves as formal notice of the federal funding I currently receive related to the hearing topic.

I received no federal funding directly supporting the subject matter on which I testified, in the current fiscal year or either of the two proceeding fiscal years.

Sincerely,

Matthew M. Nordan
Vice President of Research
Lux Research, Inc.

Chairman BOEHLERT. Thank you very much, Mr. Nordan. Dr. Doraiswamy.

STATEMENT OF DR. KRISHNA C. DORAISWAMY, RESEARCH PLANNING MANAGER, DUPONT CENTRAL RESEARCH AND DEVELOPMENT

Dr. DORAISWAMY. Good morning, Chairman Boehlert, Congressman Gordon, and Members of the Committee. My name is Krish Doraiswamy, and I am DuPont's Research Manager, Research Planning Manager, responsible for coordinating and monitoring DuPont's R&D activities in nanoscale science and engineering. I appreciate this opportunity to discuss the research needed to address the safety, health, and environmental implications of this new field.

I will focus on three main points. First, beneficial applications of nanoscale materials will emerge faster if we understand the environmental and safety implications. Second, cooperative efforts are needed to resolve key uncertainties, and I will provide examples of what DuPont is doing today to address these uncertainties. Third, there is a need for more research funding that is strategically targeted on fundamental safety, health, and environmental questions.

On the first point, with the new tools and techniques available today, we can design and fabricate new nanoscale materials that deliver entirely new properties. These new materials promise major advances in many fields. The promise of nanoscale materials also raises new questions about how they might affect safety, health, and the environment. Most of these questions are of particular relevance to nanoparticles that are engineered to exhibit new behaviors. These questions need to be addressed as new nanomaterials begin to enter the field. However, in many cases, we will need better tools and much more data to be able to answer these questions. Also, as has been pointed out, many important nanoscience discoveries and inventions are being made in universities and by startup companies, which may lack the experience and the resources to adequately address the fundamental safety, health, and environmental questions. Such broadly relevant questions should be a part of the national agenda for research in nanomaterials.

My second point is that all stakeholders need to cooperate to develop safety standards and test methods, to coordinate research and generate reliable data, and to establish appropriate oversight. DuPont is already active in several cooperative efforts. Here are some examples. DuPont coordinated the launch this year of a consortium of more than 14 industry, academic, and government organizations. This consortium is sponsoring a two-year research project that will help us understand workplace safety and health issues relating to airborne nanoparticles.

We are also working with other members of the American Chemistry Council to develop recommendations regarding safety, health, and environmental questions. We collaborate on toxicology research with the Rice University for the Center for Biological and Environmental Nanotechnology, and we are founding members of ICON, which is the International Council on Nanotechnology. We have entered into a partnership with Environmental Defense to develop a practical framework to identify, manage, and reduce potential risks of nanoscale materials, and in addition to these cooperative efforts, we have an active internal product stewardship program on nanomaterials, which includes toxicity research.

Efforts like ours are only a part of the answer. We recognize and applaud the efforts by several organizations to identify safety, health, and environmental research needs, and we look forward to the emergence of a well-considered research strategy, based on a broad scientific consensus on the key questions. In particular, we need research on the physical, chemical, and biological characterization of nanomaterials, the measurement of nanomaterials in the workplace and in the environment, understanding their environmental fate, including persistence and bioaccumulation, and developing and applying toxicity tests, including validated in vitro screening tests, where these are practical.

Lastly, we need more public funding for strategically targeted research, to complement the efforts of companies like mine. We need to quickly and systematically develop the measurement tools, test methods, and rigorous peer-reviewed data that will enable nanotechnology to deliver on its promise. This information is broadly relevant to practitioners, and needs to be openly shared within the nanotechnology community. We therefore believe that this re-

search should be publicly funded. Congress should ensure that adequate funding is provided, that the effort is strategically targeted, and carefully coordinated and actively managed.

Thank you for the opportunity to testify before you today. I will be happy to answer questions.

[The prepared statement of Dr. Doraiswamy follows:]

PREPARED STATEMENT OF KRISHNA C. DORAISWAMY

Good morning Chairman Boehlert, Congressman Gordon, and Members of the Committee. My name is Krish Doraiswamy, and I am a Research Planning Manager for DuPont Central Research & Development. In that role I am responsible for coordinating and monitoring DuPont's research and development activities in Nanoscale Science and Engineering (what we refer to as NS&E), and for developing and nurturing collaborative R&D relationships. I appreciate this opportunity to share our views on the research needed to address the Safety, Health and Environmental (SHE) implications of nanotechnology.

DuPont is a science driven company with a commitment to safety, health and environmental protection. As a 200-year-old company, we have participated in the development and evolution of many technologies, and we are proud to have contributed significantly to the advancement of scientific knowledge. At DuPont, we use science to develop products and services that improve the quality and safety of people's lives. We also use science and our commitment to safety to guide how we develop, manufacture and manage our products throughout their life cycle.

Today, my testimony will make three points:

- Broad applications of nanoscale materials will emerge faster if we understand the safety, health and environmental implications.
- Cooperative efforts are needed to resolve key uncertainties, and I will provide examples of what DuPont is doing today to address these uncertainties.
- There is a need for increased research funding that is more strategically targeted to address fundamental safety, health and environmental questions.

The need to understand SHE implications of nanoscale materials

DuPont's interest in nanoscale materials is a natural extension of our rich and deep knowledge base in materials science and its applications. The nanostructure of materials has been a fundamental determinant of a material's properties long before NS&E and nanotechnology were identified as distinct fields of study. Certain nanoscale materials (such as carbon black, pigments, magnetic storage media, and silver-based photographic chemicals) have been in commercial use for decades, or even centuries.

However, the emergence of new tools and techniques for the measurement, characterization and control of nanoscale features gives rise to many new opportunities. We can more precisely tailor known materials to more effectively deliver desired properties and to enhance functional benefits. For example, new polymer nanocomposites can be stronger, lighter, smarter and use less resources than conventional plastics. In addition, and more importantly, the new tools and techniques enable *new* generations of nanoparticulate materials and nanostructures that can create entirely new product possibilities. These new materials may, for example, enable advances in medicine, new devices and display technologies, and new approaches to energy generation and storage.

While this rapid expansion of knowledge is creating new opportunities, it is also raising new questions about nanoscale materials, and their potential impact on health, safety and the environment. Many of these questions are of particular relevance to particles that are specifically engineered to exhibit new behaviors and that measure less than 100 nanometers on at least one dimension. Such questions include:

- How do free nanoparticles with novel properties interact with the physiology of humans or other species?
- How is this interaction the same as or different from the behavior of the comparable bulk materials?
- What are the pathways by which exposure to such free nanoparticles can occur, and how can this exposure be measured and controlled?
- Do we have generally accepted tools and methods to answer these questions?

These questions must be addressed as new nanoscale materials move into the market. However, the absence of generally accepted testing methods and standards, and the lack of scientifically validated data threatens to slow down innovation and significantly delay the introduction of new products and applications. An important fact is that many of the most interesting discoveries relating to new nanoscale materials are being made in universities and by entrepreneurs in start-up companies. These entities may lack the experience, resources and funding needed to adequately address the fundamental safety, health and environmental questions. It is our belief that such broadly relevant questions should be a significant part of the national agenda for research in NS&E.

Because nanoparticles do not necessarily behave like their larger particle relatives, research is needed to develop a uniform, science-based approach for identification of hazards, assessment of exposure and management of risks. This research requires immediate attention.

The need for a cooperative effort, and what DuPont is doing

These questions are being widely discussed and considered by federal agencies, public and private special interest organizations, and in several industry, scientific, national and international forums. We believe that all parties with an interest or a stake in the responsible development and use of these new materials should work together to allow nanoscale science and engineering to reach its full potential. Specifically, we advocate collaboration in the development of responsible safety standards and test methods; the coordination of research to generate reliable, peer reviewed data; and the establishment of appropriate oversight. DuPont is leading or actively participating in programs that seek to address each of these issues. We have taken several actions in order to contribute to the responsible development and use of nanoscale materials, including:

- DuPont coordinated the launch in June 2005 of a consortium of parties interested in nanoparticle occupational safety and health. This is a multi-stakeholder consortium of more than 14 industry, academic and government organizations formed to sponsor research that will further our understanding of factors relevant to the assessment and control of occupational exposures to engineered nanoparticles.

  This two-year research project will be led by DuPont scientists and will help us understand (a) How airborne nanoparticles may behave in the workplace; (b) How to monitor and measure occupational exposures to airborne nanoparticles; and (c) How to assess the penetration of engineered nanoparticles through candidate barrier materials for personal protective equipment.

  Members of this consortium include: DuPont, Procter & Gamble, Dow Chemical, Air Products & Chemicals, Inc., Degussa, Rohm & Haas, PPG, Intel Corporation, the UK Health & Safety Executive, and the Department of Energy Office of Science.
- We are working with a broad industry group (the Chemstar Panel on nanomaterials, within the American Chemistry Council). This panel is developing recommendations for the EPA and for the chemical industry regarding safety, health and environmental issues and regulatory guidelines for nanoscale materials. As part of this effort, we participated with the Ad Hoc Nano Working Group of the U.S. EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to develop options for the EPA regarding a voluntary reporting program to share and generate data on nanoscale materials.
- We are supporting research at the Rice University Center for Biological and Environmental Nanotechnology (CBEN), and are founding members of ICON, the International Council on Nanotechnology, also based at Rice University. ICON is a multi-stakeholder group, with representation from industry, academia, regulatory and non-governmental organizations to "assess, communicate, and reduce nanotechnology environmental and health risks while maximizing its societal benefit." More information about ICON is available at *www.icon.rice.edu.*
- We have entered into an agreement with Environmental Defense to jointly develop a framework that can be used to identify, manage and reduce potential health, safety and environmental risks of nanoscale materials across all life cycle stages. This work is just getting started, and we expect to consult extensively with other stakeholders during the project.

- In addition to these cooperative efforts, We have an active internal Product Stewardship program on nanomaterials, including toxicity assessments of lung responses. We are studying nanomaterials in commercial development as well as generic nanoscale particles, and comparing their effects to standard reference particle-types.

In summary, we are dealing with nanoparticle SHE questions as a work in progress on many fronts, with broad engagement of other stakeholders to develop robust guidelines.

However, these efforts go only part of the way toward developing the strong foundation of knowledge and tools that are needed by the NS&E community. Fortunately, there has been progress on other fronts. For example, a report issued last month by the International Life Sciences Institute Research Foundation/Risk Science Institute (ILSI), and funded by the EPA, recommends the first elements of a screening strategy to characterize the potential human health effects from exposure to nanomaterials. DuPont toxicologist David Warheit was a contributor to the development of the ILSI report.

DuPont applauds these efforts to carefully define the research that is needed, and we believe they provide a good initial foundation for a broad SHE-focused research strategy. We believe that broadly representative organizations such as the National Academy of Sciences could play a role in the further development of this strategy. In particular, we endorse the pressing need for research in the following areas:

- Understanding the critical physical, biological, and chemical parameters that characterize nanomaterials;
- Measuring, at an appropriate level, the presence of nanomaterials in the environment and particularly in the workplace;
- Understanding and predicting the environmental fate of nanomaterials with particular attention to persistence and bioaccumulation;
- Developing toxicity tests for hazard assessment of nanomaterials, with particular attention to validated in vitro screening tests, to the extent practical, and applying these tests to establish baseline criteria for evaluation of nanomaterials.

The need for increased and strategically targeted SHE research funding

In our opinion, the research that has the highest priority relates to the development of the practical knowledge base that is described above, and the development of tools and methods that are broadly relevant to practitioners which can be widely shared within the NS&E community. We, therefore, believe that this area of research should be publicly funded.

The same message was delivered by DuPont's Chairman & CEO and the President of Environmental Defense, in an article they co-authored earlier this year in *The Wall Street Journal.* To quote from this article, "Our government also needs to invest more seriously in the research necessary to understand fully nanoparticle behavior."

However, the challenge is greater than the mere allocation of additional funds for SHE research. The mechanism by which federal research funds are allocated today for NS&E is designed to support and accelerate discovery and innovation across a wide spectrum of autonomous agencies, and to foster unfettered creativity in identifying new innovation opportunities. However, we believe that there is a better model for supporting research relating to SHE questions. A more actively managed, strategically targeted, and carefully coordinated approach is needed to achieve our common goal. This goal is to systematically develop the measurement tools, test methods and rigorous, peer-reviewed data that will enable nanotechnology to deliver on its promise. The preferred SHE research model would, therefore, take a more prescriptive approach to the selection and prioritization of research topics, and would establish metrics to measure progress against defined targets.

In conclusion:

- We believe that Nanoscale Science and Engineering is an important field of knowledge, with rich potential to enable breakthrough innovations that improve the quality of life in many sectors. To fully realize this potential, we need to understand the SHE implications of nanoscale materials.
- Systems need to be agreed and established through a cooperative effort among all the stakeholders, to address and resolve the key uncertainties, and to provide appropriate mechanisms for risk assessment and risk management.
- DuPont is already collaborating actively on the development of a rigorous and consistent terminology, screening strategies, workplace safety measurements

and controls, and a framework to define a systematic and disciplined process to identify, manage and reduce potential SHE risks of nanoscale materials across all life cycle stages.

- Federal and private funding for research that addresses safety, health and environmental concerns needs to be coordinated and strategically targeted to achieve the maximum impact in the shortest time.

Thank you. I will be happy to answer any questions.

BIOGRAPHY FOR KRISHNA C. DORAISWAMY

Dr. Doraiswamy is responsible for identifying opportunities to maximize the value of DuPont's R&D portfolio in nanoscale science and engineering, and for developing and nurturing collaborative R&D relationships with external entities. He serves on the ANSI–Accredited U.S. Technical Advisory Group to the ISO committee developing nanotechnology standards. He also serves on the ASTM Nanotechnology Committee, and has served on the Business Advisory Board of the California NanoSystems Institute (CNSI).

During his 24 years in DuPont, Dr. Doraiswamy has been actively engaged in the development and commercialization of new technologies in new business domains. Dr. Doraiswamy has held various prior assignments in marketing, strategic planning and business development. He played a leadership role in establishing several early stage business ventures within DuPont, including DuPont Photonics Technologies, Qualicon (rapid pathogen detection systems), and DuPont Holographic Materials. In all of these ventures, he was responsible for setting up mission-critical business and technology alliances with other major corporations and with start-ups.

Dr. Doraiswamy received his Bachelor's degree in Chemistry from Imperial College, London. He has a Ph.D. in Chemistry and an MBA with a concentration in Marketing from Carnegie Mellon University.

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November 15, 2005

The Honorable Sherwood Boehlert
Chairman, Science Committee
2320 Rayburn Office Building
Washington, DC 20515

Dear Congressman Boehlert:

Thank you for the invitation to testify before the Committee on Science of the U.S. House of Representatives on November 17th for the hearing entitled "Environmental and Safety Impacts of Nanotechnology: What Research is Needed?" In accordance with the Rules Governing Testimony, this letter serves as formal notice of the federal funding I currently receive related to the hearing topic.

I received no federal funding directly supporting the subject matter on which I testified, in the current fiscal year or either of the two proceeding fiscal years.

Sincerely,

Krishna C. Doraiswamy
Research Planning Manager
DuPont Central Research and Development

Chairman BOEHLERT. Thank you very much, Mr. Rejeski.

STATEMENT OF MR. DAVID REJESKI, DIRECTOR, PROJECT ON EMERGING NANOTECHNOLOGIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS

Mr. REJESKI. I would like to thank Chairman Boehlert, and Ranking Member Gordon, and Members of the House Committee for holding this hearing.

Before I share my ideas with you, I thought I would like to share some observations from a group that really tends to be under-represented. These are quotes from a group in Spokane, Washington that we met with on nanotechnology in June. I quote: "I found it interesting that so many government agencies are potentially responsible for nanotechnology. With so many agencies, bureaucracy enters the process because everybody is fighting over who is responsible." Terrence added, "until something goes wrong." At that

point, there was a lot of laughter in the room. Mickey came back with "then nobody wants the responsibility." What kind of gridlock does that cause?

In every focus group we carried out across America, people talked as much about governance as they talked about science and technology. The public is asking our government to answer four basic questions. The first one, do we understand the risks associated with nanotechnology, both today's risks and tomorrow's? Second, will our policies protect us and the environment from these risks? Third, when and how will you, the government, start talking to us about what you are doing, what you know, and what you do not know? And finally, if something goes wrong with this technology, are you prepared?

Let me address each of these challenges in order. Are we spending enough to understand the risk to workers, consumers, and the environment? I cannot tell you the answer to that. I can tell you what is needed to address this issue. We need a full, transparent disclosure of all government-funded environmental, health, and safety-related research, every single project, not just the monetary sum of the projects. This will allow us to identify gaps, to better partner with industry and government in other countries to fill the gaps, and strategically invest or disinvest at the margins. We live in a world of fiscal constraints, so we can't assume that we are going to have another $100 million to spend on this.

Right now, we are in the process of putting together this inventory, and we will release such an inventory on November 29. We would like to request the committee that they keep the docket open until the end of the month, so we can submit essentially our initial analysis of the main research gaps. But that is not going to be enough. We are going to be dealing with the risks of nanotechnologies for decades to come. These risks are going to become more complex, not simpler, especially as nano and biotechnology converge. No single country will ever have enough money to address these risks.

I believe that it is time to essentially start an International Nanorisk Characterization project that is modeled roughly on what we did with the Human Genome Project, where we essentially prioritize risks on a global level, align teams of researchers to address these priorities, and we implement an information infrastructure to support global collaboration. In the end, we are going to have to leverage every single dollar, every single euro, every yen, everything that we have, both government and industry.

The public wants to know: will our oversight and regulatory policies protect us? I do not think anybody in this government right now can provide a clear answer, and certainly, the public, I can tell you, is not confident. Our approach to the policies have been, so far, ad hoc and incremental, and we need a systematic analysis across agencies, statutes, and programs, across agencies, and across the entire international landscape, which looks at regulations, voluntary agreements, information-based strategies, State and local ordinance, and ask this question: will this work now, will it work five years from now, and will it work 10 years from now? I am especially concerned that we lack any kind of coherent strategy to reach small businesses and startups with the appropriate in-

formation they are going to need to protect workers and the environment.

Now, it is time, I think, to ask the Government Accountability Office, as you asked the National Academy of Sciences two years ago, the National Academy of Public Administration to undertake within one year a systemic analysis of the government structure for nanotechnology issues, and develop a government-wide, and I stress government-wide, blueprint for the regulation and control of these technologies that will work not only today, but 10 years from now, and 20 years from now. I think we owe that to consumers, to workers, and also to industry.

The Federal Government and industry also has to address what Mr. Nordan called perception risks. In the end, the success of these technologies will depend on the public opening its mind and its pocketbook and embracing technologies. It is not a given, as we learned with nuclear power and with genetically modified organisms. Studies show that people are excited about these technologies, but they have little trust right now in either government or industry to manage the risks, and consistently ask for more transparency. They want more disclosure, and they want more involvement. We need to engage the public, not just try to educate them.

The U.S. Government should set a goal to reach out and engage at least 3,000 citizens and public opinion leaders around the country over the next year. This would require 20 to 25 town meetings, listening sessions, and civic forums, but I think it would help build the foundation we need for greater public trust, confidence, and acceptance of these nanotechnologies, and ultimately, create more viable and growing markets.

Finally, we need to prepare for the unexpected. Nanotechnology is essentially planned disruption. It is not something we want to get smug or overconfident about. We could be surprised in unpleasant ways, either by the technology itself, or by people who mishandle it, mislabel it, or misuse the technology. So we do anticipate and plan for and rehearse every possible scenario for misuse or accidents. I see no evidence whatsoever that this is happening anywhere in the government right now.

In conclusion, let me emphasize that to succeed, we are going to need two things. We need good science, and we need good governance. Our project through the Wilson Center looks forward to working with this committee as you move forward.

Thank you.

[The prepared statement of Mr. Rejeski follows:]

PREPARED STATEMENT OF DAVID REJESKI

I would like to thank Chairman Sherwood Boehlert, Ranking Member Bart Gordon, and the Members of the House Committee on Science for holding this hearing on the environmental, health, and safety (EH&S) implications associated with the development of nanotechnology.

My name is David Rejeski, and I am the Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. This Project was created earlier this year in partnership with The Pew Charitable Trusts.

The Project on Emerging Nanotechnologies is dedicated to helping ensure that as nanotechnologies advance, possible risks are minimized, public and consumer engagement remains strong, and the potential benefits of these new technologies are

realized. The Project collaborates with researchers, government, industry, non-governmental organizations (NGOs), and others concerned with the safe applications and utilization of nanotechnology.

Our goal is to take a long-term look at nanotechnologies, to identify gaps in the nanotechnology information, data, and oversight processes, and to develop practical strategies and approaches for closing those gaps. We aim to provide independent, objective information and analysis that can help inform critical decisions affecting the development, use, and commercialization of nanotechnologies throughout the globe.

In short, both the Wilson Center and The Pew Charitable Trusts believe there is a tremendous opportunity with nanotechnology to "get it right." Societies have missed this chance with other new technologies and, by doing so, have made costly mistakes. We think nanotechnology's promised benefits are so great that we do not believe the United States and the rest of the world can afford to miscalculate or misstep with nanotechnologies.

As the Committee knows, nanotechnology is expected to become the transformational technology of the 21st century. It is the world of controlling matter at the scale of one billionth of a meter, or around one-100,000th the width of a human hair. Researchers are exploring new ways to see and build at this scale, re-engineering familiar substances like carbon and gold in order to create new materials with novel properties and functions.

As the National Science Foundation (NSF) highlights, the ability to determine the novel properties of materials and systems at this scale implies that nanotechnology eventually could impact the production of virtually every human-made object—everything from automobiles, tires, and computer circuits to advanced medicine and tissue replacements—and lead to the invention of products yet to be imagined. Nanotechnology will fundamentally restructure the technologies currently used for manufacturing, medicine, defense, energy production, environmental management, transportation, communication, computation, and education.[1]

NSF predicts that the world market for goods and services using nanotechnologies will grow to $1 trillion by 2015. Lux Research calculates that in 2004 there were $13 billion worth of products in the global marketplace incorporating nanotechnology.[2] Others estimate there are already over 700 products on the market that are made from or with nanotechnology or engineered nanomaterials. Worldwide about $9 billion annually is being spent by governments and the private sector on nanotechnology research and development.

1. What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?

In the midst of the tremendous excitement over nanotechnology that exists in university research laboratories, government agencies, and corporate boardrooms, publics throughout the world remain largely in the dark. A major study, funded by NSF and conducted in 2004 by researchers at North Carolina State University (NCSU), found that 80–85 percent of the American public has heard "little" or "nothing" about nanotechnology.[3] This is consistent with similar polling results in Europe and Canada. Anecdotally, some researchers believe that an even higher percentage of the public remains uninformed about nanotechnology.

Earlier this year (2005), the Project on Emerging Nanotechnologies commissioned a new report by Senior Associate Jane Macoubrie, who co-authored the NCSU study in 2004. This new report, "Informed Public Perceptions of Nanotechnology and Trust in Government," provides an in-depth look at what Americans know and do not know about nanotechnology.[4]

It indicates that U.S. consumers, when informed about nanotechnology, are eager to know and learn more. They generally are optimistic about nanotechnology's potential contribution to improve quality of life. The key benefits

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[1] M.C. Roco, R.S. Williams and P. Alivisatos. *Nanotechnology Research Directions: IWGN Workshop Report.* Berlin, Germany: Springer, 2000, p. iii–iv.

[2] "Sizing Nanotechnology's Value Chain." New York, NY: Lux Research, October 2004.

[3] Michael D. Cobb and Jane Macoubrie. "Public Perceptions about Nanotechnology: Risk, Benefits and Trust." Raleigh, NC: North Carolina State University, 2004. Available at *http://www2.chass.ncsu.edu/cobb/me/past%20articles%20and%20working%20papers/Public%20Perceptions%20about%20Nanotechnology%20-%20Risks,%20Benefits%20and%20Trust.pdf.*

[4] Jane Macoubrie. *Informed Public Perceptions of Nanotechnology and Trust in Government.* Washington, DC: Woodrow Wilson International Center for Scholars, 2005. Available at *http://www.wilsoncenter.org/news/docs/macoubriereport1.pdf.*

the public hopes for are major medical advances, particularly greatly improved treatment for cancer, Alzheimer's, and diabetes.

The Project's report findings track closely with work done last year (2004) by University of East Anglia researcher Nick Pidgeon for Great Britain's Royal Society. Pidgeon found there were few among the British public who knew much about nanotechnology. Those that did were optimistic that it would make life better. Study participants expressed concern about privacy issues and about the high costs of nanotechnology research and development to the British taxpayer. Some Britons also feared that nanotechnology would turn out to be a case of "scientists trying to play God"—a phrase frequently attributed to the Prince of Wales in the press.[5]

This general public optimism about nanotechnology is what I consider the "good news." In the NCSU study, only 22 percent of the U.S. participants believed that nanotechnology's risks would exceed its benefits. The rest anticipated nanotech's benefits would exceed risks (40 percent), or expected risks and benefits to be about equal (38 percent).

The "bad news" is that both the recent Project on Emerging Nanotechnologies report and last year's NCSU study highlight "no" or "low" American public trust in government and industry to manage any potential risks associated with nanotechnology. This is important because, both at home and abroad, the public's risk tolerance is weighed against a technology's direct benefit to them or to a group of people they consider important—children, senior citizens, the sick, the poor, and the disadvantaged. It also is highly dependent on their confidence or trust in the people making decisions about the technology's development, commercialization, and regulation.

Worse, the Project on Emerging Nanotechnologies' report showed that a lack of knowledge—about nanotechnology-based products, about possible health and environmental implications, and about the oversight process designed to manage any potential risks—breeds U.S. public mistrust and suspicion. In the absence of balanced information, people are left to speculate about the possible health and environmental impacts of nanotechnology. Rightly or wrongly, without information, they often draw on analogies of what they consider past failures to effectively manage risks—like dioxin, Agent Orange, or nuclear power.

A *Nature* magazine editorial described this Project report—along with a recent U.K. citizens' jury conducted by the universities of Cambridge and Newcastle—as providing governments with some "direct public guidance on citizens' interests that must be protected if nanotechnology is to flourish."[6] For policy-makers, the "take home" messages from a number of studies are quite clear:

- Consumers want more information to make informed choices about nanotechnology's use and greater citizen engagement in shaping how the technology is developed.
- There are low levels of trust in government and industry to manage any risks associated with nanotechnology. There is little support for industry self-regulation or voluntary agreements. A majority of the public believes that mandatory government controls are necessary.
- People have clear ideas about how to improve trust. They want government and industry to practice *due diligence* to ensure manufacturing and product safety. In both U.S. and U.K. studies, this translated into strong support for research and safety testing before products go to market and a focus on better understanding long-term effects on both people and the environment.

In my view, there is still time to inform public perceptions about nanotechnology and to ensure that nanotechnology is developed in a way that citizens—as well as the insurance industry, corporate investors, NGOs, and regulatory officials—can trust. However, with the production of nanosubstances ramping up and more and more nanotech-based products pouring into the marketplace, this window is closing fast. Industry remains concerned about the possibility of liability for nanoproducts with unknown risks in an uncertain regulatory environment. Coordinated education and engagement programs will be needed, supported by both government and industry. These programs will have to be structured to reach a wide range of consumers, cutting across age, gender, and socioeconomic status, utilizing a variety of media going beyond tradi-

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[5] *Nanotechnology: Views of the General Public.* London, U.K.: BMRB Social Research, January 2004, BMRB/45/1001–666. Available at *www.nanotec.org.U.K./Market%20Research.pdf.*

[6] "Value-free nanotech?" *Nature* 437, September 22, 2005, 451–452.

tional print, radio, television, film towards non-traditional media such as blogs and multi-player on-line games.

2. What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?

Over the past 15 years, scientific data on the health and environmental impacts of nanostructured materials has been growing slowly. Three scientific reviews of the subject recently have been written, each of which notes that while some initial information as to environmental, health, and safety (EH&S) implications is available, much more work remains to be done in this area.

One overview of the subject by Günter, Eva, and Jan Oberdörster notes that laboratory studies have shown that airborne nanoscale materials depositing in the respiratory tract can cause an inflammatory response when inhaled.[7] The small size of engineered nanomaterials also makes it easier for their uptake into and between various cells, allowing for transport to sensitive target sites in the body, including bone marrow, spleen, heart, and brain. Various kinds of nanomaterials, including C–60 fullerenes, single-walled nanotubes, and quantum dots, have been found to mobilize to mitochondria in cells, potentially interfering with antioxidant defenses. However, the translocation rates of these materials are uncertain.

In addition, Oberdörster *et. al.* report that there have been only a few studies looking at the effects of engineered nanomaterials on environmental systems. Water-borne carbon-60 was found to lead to oxidative stress in the brains of largemouth bass, although the mechanisms of action were uncertain. The bactericidal properties of carbon-60 in water have also been reported, and are being used as potential new anti-microbial agents. However, such uses may have unforeseen consequences on delicate ecosystems if materials are released into the environment. Quoting the authors, "During a product's life cycle (manufacture, use, disposal), it is probable that nanomaterials will enter the environment, and currently there is no unified plan to examine ecotoxicological effects of [nanoparticles]."[8]

An article by Andrew Maynard and Eileen Kuempel[9] on the impact of airborne nanostructured particles on occupational health notes that while a number of studies have investigated the toxicity and exposure of ultrafine aerosols, there are currently no studies on exposure and response to engineered nanomaterials in humans. Nevertheless, our experience with ultrafine aerosol particles (particles smaller than 100 nm that are typically a by-product of a process) in the workplace has shown that inhalation of micro- and nano-sized fibers and particles can lead to increased rates of cancer, lung disease, and adverse respiratory symptoms.

In addition to size, the shape, solubility, surface chemistry, and surface area of ultrafine particles is known to increase inflammation and tissue damage. These are not properties that are usually considered when evaluating hazards and health impacts. **While it should be emphasized that little data exists in relation to the human health impact of these factors for engineered nanomaterials, similar responses can be expected and appropriate risk-management strategies will be needed.**

Finally, a recent paper sponsored by the International Life Science Institute[10] (ILSI) highlights a number of these points by noting that the unknowns and uncertainties surrounding the current state of EH&S research imply that "there is a strong likelihood that biological activity of nanoparticles will depend on physiochemical parameters not routinely considered in toxicity screening studies." In short, the report concludes that "little knowledge exists regarding specific nanomaterial characteristics which may be indicators of toxicity," requiring additional investigations into the physiochemical characterization of these materials and the development of accurate *in vitro* and *in vivo* testing methods.

Overall, a comparative reading of these three overview articles and other published studies elucidates a number of key points, including:

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[7] Günter Oberdörster, Eva Oberdörster, Jan Oberdörster. "Nanotoxicology: An Emerging Discipline Evolving for Studies of Ultrafine Particles," *Environmental Health Perspectives,* July 2005, 113(7): 823–839.

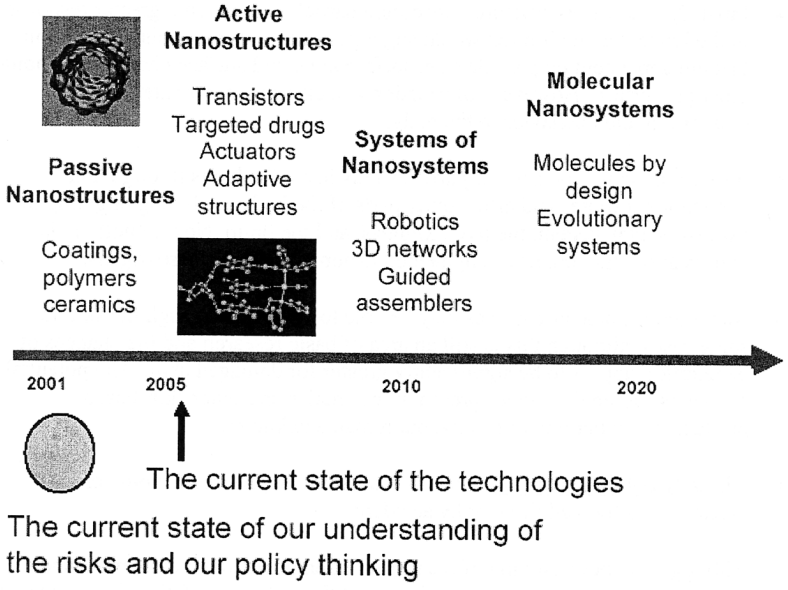
[8] Günter Oberdörster, Eva Oberdörster, Jan Oberdörster, p. 836.

[9] Andrew Maynard and Eileen Kuempel. "Airborne Nanostructured Particles and Occupational Health," *Journal of Nanoparticle Research,* 2005, forthcoming.

[10] Günter Oberdörster et. al. "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy," *Particle and Fibre Toxicology,* October 2005, 2(8):1–35.

- Since engineered nanomaterials show behavior that depends on their physical and chemical structure, risk assessment paradigms that have been developed based on traditional, bulk chemistry alone may no longer be valid.
- Inhaled, nanometer-structured, insoluble particles can elicit a greater response in the lungs than their mass would suggest, indicating mechanisms of action that are dependent on particle size, surface area, and surface chemistry, among other properties. However, information is lacking on nanomaterials' structure-related behavior in the body.
- Inhaled, nanometer-diameter particles may leave the lungs through non-conventional routes and affect other parts of the body, including targeting the cardiovascular system, the liver, kidneys, and the brain. Next to nothing is known about the impact of engineered nanomaterials on these organs.
- Nanometer-diameter particles may be able to penetrate through the skin in some cases, although this is still an area of basic research and the chances of penetration appear to be significantly greater for damaged skin. The potential for nanostructured particles present in cosmetics and other skin-based products to do harm may be low, but remains unknown.
- *Virtually nothing is known* about the hazard of engineered nanomaterials ingested as a food additive or by accident.
- Although an understanding of the impact of engineered nanomaterials and nano-enabled products on the environment through their lifetime is considered critical, virtually nothing is known at present.

Much of the research undertaken so far has raised more questions than answers. To date, the majority of research has focused on relatively basic engineered nanomaterials. As nanomaterials move from simple to complex materials and on to active and multi-functional materials, major knowledge gaps need to be filled before useful quantitative risk assessments can be carried out and before comprehensive, life cycle risk management strategies can be developed. As the image below indicates, the technology is developing more rapidly than our understanding of the EH&S risks and our ability to respond with effective policy measures.



Timeline adapted from Roco, M., National Science Foundation

3. What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?

A number of groups have developed, or are in the process of developing, lists of research priority areas and questions of interest. These organizations include the National Institute for Occupational Safety and Health (NIOSH)[11], Environmental Defense[12], the Semiconductor Research Corporation, and the Chemical Industry Vision 2020 Technology Partnership.[13] Despite the diversity of these organizations, these gap analyses are generally in broad agreement on the areas requiring further research and development. Common themes include: Toxicity (human and environmental), exposure and material release/dispersion, epidemiology, measurement and characterization, control of exposure and emissions, safety hazards, risk management models, and product life cycle analysis.

There also appears to be agreement that the federal support for risk-related EH&S research has been spread too thin. As a result, EH&S research currently lacks enough depth to adequately address and provide substantial answers to many risk management questions that will emerge in both the near and long-term future. Therefore, an effective, forward-looking, internationally recognized EH&S research strategy needs to be developed to fill this gap.

A major barrier to developing a coherent risk-related research agenda of sufficient breadth and depth—within government and in conjunction with the private-sector—is a lack of coordination and information about the risk-related research the government is *currently* supporting.

To address this issue, **the Project on Emerging Nanotechnologies is in the process of compiling a publicly accessible inventory of government-supported, risk-related research—both domestically and internationally—that is addressing the EH&S implications of nanotechnology.** It is our hope that this inventory will be a useful tool for informing future EH&S-related research strategies and policy decisions. Although not comprehensive, it will provide the most complete overview of current federally funded research into the EH&S implications of nanotechnology to date.

The first generation of this inventory contains basic information on government-funded, risk-related research projects, including summaries, outputs, duration, funding sources, and budgets. The research is categorized on multiple levels. The first layer of categorization analyzes each research project by its relevance to the implications of nanotechnology, whether the nanomaterials under investigation are intentionally manufactured, incidental or naturally occurring, and whether the primary focus is on human health, environment, or safety impacts. A second layer of categorization classifies the research according to its focus within a simplified risk analysis framework. Finally, provision is made for a more detailed, third level of classification according to a range of searchable keywords and phrases.

As of early November, the inventory included a total of 154 ongoing and completed projects in the United States, accounting for roughly $23 million per year of federally funded research across eight different agencies. The inventory also currently includes 15 projects from sources around the world, including Canada, the U.K., and EU countries, accounting for roughly $2.6 million per year.

This inventory will be made available online on November 29th and will include our initial analysis of research gaps. We would like to submit our preliminary analysis of the federal EH&S research portfolio to this Committee and request that the docket be held open until then, if possible. Additions to the inventory will be made as new information is received, and researchers and research managers will be encouraged to contribute new or updated information as their work progresses. The inventory is currently undergoing external peer review, along with internal checks for accuracy.

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[11] National Institute for Occupational Safety and Health. *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps.* September 28, 2005. Available at *http://www.cdc.gov/niosh/topics/nanotech/strat_—planINTRO.html.*

[12] Richard A. Denison. "A proposal to increase federal funding of nanotechnology risk research to at least $100 million annually." Washington, DC: Environmental Defense, April 2005. Available at *http://www.environmentaldefense.org/documents/4442_100milquestionl.pdf.*

[13] Semiconductor Research Corporation and Chemical Industry Vision 2020 Technology Partnership. "Joint NNI–ChI CBAN and SRC CWG5 Nanotechnology Research Needs Recommendations."

There are a number of key advantages provided by the inventory:

- It can enable the coordination of research between disciplines, agencies, and various stakeholders. It can also enable the coordination of research internationally, reducing the probability of duplicative research in different countries.
- It will allow the government to develop an integrated set of EH&S policies that are designed to make strategic investments based upon what work is already being undertaken. By helping to identify where the need for further funding lies, the current gaps in the EH&S research portfolio can be more easily addressed.
- It will satisfy the public's desire for greater transparency and disclosure of government activities, a desire that has been voiced repeatedly in the surveys and public perception studies discussed earlier.
- It will allow for the government to form partnerships with industry around pre-competitive research, as it becomes evident which exposure and toxicity issues are of interest to firms in the early stages of commercialization. Joint funding for EH&S research would be seen as a broad-based, long-term investment in nanoscale science and technology and would greatly increase our understanding and ability to manage potential risks.

Preliminary analysis of the data indicates that most critical research gaps are being addressed to a certain extent. However, it is also apparent that coverage of these issues is very limited, patchy, and uncoordinated. Research into exposure and hazard evaluation is relatively well represented in the database, and there are a number of projects providing information on nanomaterials' behavior that may determine impact. Research into how to control nanomaterials' releases and exposure effectively is being undertaken, and to a lesser extent, research into risk assessment and management methods and models.

The areas of research that are under-represented by comparison are human health effects and environmental impact, and human safety (such as fire and explosion hazards). It is also apparent that much of the current research portfolio focuses on first generation engineered nanomaterials, with very little strategic research addressing more complex materials currently under development. NIOSH, EPA, and NSF are leading the research highly relevant to the environmental, health, and safety implications of engineered nanomaterials, with DOD also making a significant contribution. Investigator-driven research funded by all four agencies is dominating mission-driven research addressing EH&S issues—raising questions over the degree to which currently funded projects address strategic issues.

Evaluating the number or value of research projects addressing specific issues in isolation does not provide insight into research gaps and strategy limitations. However, when used in conjunction with complementary information on research and oversight needs, it provides a powerful tool for developing informed, focused, and long-range strategies.

Third, in addition to the need for increased funding and coordination, our analysis of the inventory data raises a host of more difficult questions related to structural issues. Does a trained workforce exist both domestically and internationally to undertake such novel research? Do governments have adequate human resources and the cooperative mechanisms necessary to manage such an effort effectively? Is there sufficient international agreement on technical definitions, metrology, and testing frameworks to collaborate and evaluate risk-related research among many countries?

At this point, it is uncertain as to whether this emerging policy response to concerns over nanotechnology's EH&S implications will be able to match the pace of innovation. As developments in nanotechnology become more revolutionary, transformative, and discontinuous, the governance system must adjust and change accordingly. Failure to do so will perpetuate the public's low trust in the government's ability to manage technological risk.

4. Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

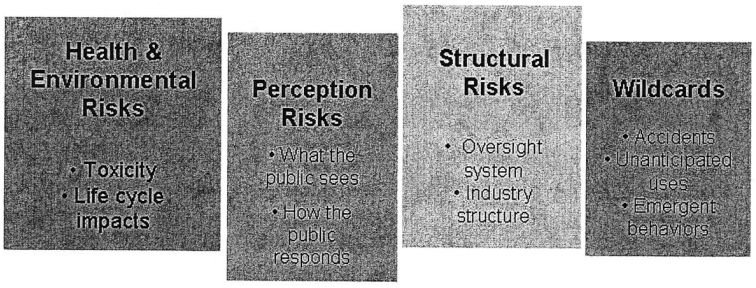
Our ability to realize the promise of nanotechnology is becoming more and more linked to governance and management issues, not just science.

The country that wins the global nanotech race will be the country that can manage a suite of potential risks and challenges involving pubic perception, effective

oversight, and the possibility of surprise. Understanding the environmental and health risks is a necessary *but insufficient* condition for success.

If the goal of the National Nanotechnology Initiative is ultimately the creation of economic value, jobs, and innovative products that can change people's lives, we need a larger perspective on the tasks ahead and, in all probability, newer and smarter management and governance approaches that go beyond "another interagency workgroup." Let me discuss the risks we face as a society using a broader framework that goes beyond EH&S issues. I will focus on areas we need to tackle, and discuss what the Federal Government, along with other key stakeholders, might do.

Framework for Nanotechnology-Related Risks



Health and Environmental Risks

From a global perspective, the U.S. Government has responded early and comparatively well to the EH&S challenge. As I outlined earlier, there are gaps in knowledge that must be closed and this requires more open debate and cooperation with industry and other countries. We need to acknowledge that the fiscal constraints we face in this country and elsewhere may limit our ability to significantly increase research dollars. As the analyses by the American Association for the Advancement of Science have indicated, U.S. funding for environmental research has been flat (in real terms) for more than 20 years. The existence of very real fiscal constraints means that effective management of the EH&S research enterprise for nanotechnologies is imperative, not optional. Every dollar, every euro or yen matters, and must be leveraged. The United States should take the lead by putting our research cards on the table so we can build winning hands with other countries and industry.

I strongly feel it is time to launch an International Nanorisk Characterization Initiative (modeled roughly on the Human Genome Project) where we develop priorities across countries, align teams of researchers to address these priorities, and implement an information infrastructure to support global collaboration. Engaging industry in supporting pre-competitive research projects in this portfolio will also be necessary. The risk characterization challenges we face today are relatively easy compared to what will come as nanotechnology and biotechnology converge and as we build ever-more complex and multi-functional nanostructure and systems of nanostructures. We are at the bottom of a very steep learning curve.

Perception Risks

Recently, a number of reports from the financial sector have underscored the importance of addressing and managing perception risks related to how the people perceive nanotechnologies.[14] In the end, the success of nanotechnologies will depend on the public opening its mind and pocket book and embracing nanotechnology. This

[14] Lux Research. *A Prudent Approach to Nanotech Environmental, Health and Safety Risks.* 2005 and Innovest Strategic Value Advisors. *Non-traditional Methods for Valuation of Nanotechnology Producers: Introducing the Innovest Nanotechnology Index for the Value Investor,* 2005. *http://www.innovestgroup.com/.*

is not a given, as we have learned from other technologies such as genetically engineered foods and nuclear power. Recently, pharmaceutical companies have seen profits erode because of declining public trust in their organizations and products.[15]

Based on the public perception studies from multiple countries, which I summarized earlier, the public has clearly articulated their concerns about nanotechnologies and what they expect from government and industry. To summarize this, they are asking for better *due diligence* involving standardized testing (preferably by independent third parties), greater transparency, and the disclosure of test results.

The public's willingness to tolerate risks from new technologies also is linked to the perception of early and significant benefits. The large-scale benefits from nanotechnology have not yet materialized and may not for 3–10 years. For the foreseeable future, I believe there will be little public tolerance of oversight failures or mishaps, either in the United States or in most European countries. A mishap could rapidly chill investment and galvanize public opposition. More civil society actors are becoming aware of nanotechnologies and carefully watching both government and industry response to possible risks.

How growing numbers of the public learn about nanotechnologies, from whom, and with what message, may be critical in shaping long-term popular acceptance. The U.S. Government needs a public engagement strategy, which is not the same as education. Educating people on nanotechnology assumes there is a deficit in their understanding. Engagement forces us to admit that the public may have something important to say to scientists, industry, and policy-makers and that they deserve being part of the larger conversation about how nanotechnology develops. Engagement cannot be a public relations campaign. As Physicist Richard Feynman once noted, "For a technology to succeed, reality has to take precedence over public relations."

The U.S. Government, for example, should set a goal of engaging at least 3,000 citizens and public opinion leaders around the Nation over the next year. This would require 20–25 town meetings, "listening sessions," and civic forums, but it would be time and money well spent and would help to raise public awareness and public confidence. Associated with this effort, we also need to establish an ongoing and scientifically robust mechanism to track public knowledge and attitudes toward nanotechnology over time (on a regular six-month basis, for instance). Let's call this a NanoBarometer—designed to take the pulse of the public and to continually monitor and help to evaluate our public engagement efforts.

Industry also plays a critical role in shaping perception risks. Few companies have talked openly about their involvement with nanotechnology, no doubt because of large uncertainties concerning public reaction and government regulatory intentions, but this situation needs to change. In the long run, silence is likely to breed suspicions and mistrust on the part of the public.

Structural Risks

With more and more nanotech-based products entering commerce, a key question is whether significant gaps exist in our oversight structure and how we can address these. Though agencies have been meeting to discuss oversight and the EPA has begun developing a voluntary program, our approach on the regulatory side so far has been ad hoc and incremental. **It is particularly worrisome that many nanotechnology-based products are entering the market in areas with little, or no, government oversight,** such as cosmetics and consumer products. The U.S. Government approach has been limited by the following:

- A focus on single statutes such as the *Toxic Substances Control Act* (TSCA) rather than taking an integrated, multi-statute approach
- A focus on products more than the facilities and processes where production occurs
- A general lack of concern with the full life cycle impacts of emerging nanotechnologies (an approach recommended in the U.K. Royal Society Report)[16]

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[15] "Big Drug Makers See Sales Erode with Their Image." *The New York Times.* November 14, 2005, p. A1. This article cites a recent poll that shows only nine percent of Americans believed that drug companies were generally honest.

[16] *Nanoscience and nanotechnologies: opportunities and uncertainties.* London, U.K.: The Royal Society and Royal Academy of Engineering, July 2004. Available at *http://www.nanotec.org.U.K./finalReport.htm.*

- Too few resources devoted to pollution prevention and the "greening" of nanotechnology products and production processes, which could help industry ultimately avoid potential risks from the beginning
- Too little discussion of the resource constraints to effective oversight (for instance, do we have the personnel and dollars in the agencies needed for enforcement or testing?).

Most important, we have not looked forward to consider where nanotechnology is heading, assuming decades-old policies and analogies to the past will help us respond to the risks of the future. Today, nanotechnology is largely chemistry. But in a very short time, it will be chemistry and biology, and after that we will be dealing with multi-functional machines operating at the interface of classical and quantum physics.

Many of the assumptions that governed our approach to chemicals regulation may no longer hold. Because the risks of nanomaterials are poorly related to mass (and depend on other characteristics like surface volume, chemistry, charge, etc.), governments and industry will have to rethink the mass-based approaches that have historically shaped our toxicology, regulations, and regulatory-related monitoring systems.

We need a systemic analysis across agency statutes and programs, across agencies, and across the international landscape. This should include existing regulations, voluntary programs, information-based strategies, state and local ordinances, and tort law. All these measures need to be evaluated not just in terms of their applicability to nanotechnology today, but also in terms of their efficacy in five or ten years. We need an oversight blueprint that is proactive, transparent, and, for industry, predictable both now *and into the foreseeable future.*

In 2003, the Congress asked the National Academy of Sciences to evaluate the National Nanotechnology Initiative, largely from the perspective of the science. We urgently need to examine the governance. **Now it is time to ask the General Accountability Office or National Academy of Public Administration to undertake (within one year) a systematic analysis of the governance structure for nanotechnologies and develop a government-wide blueprint that will work not only today, but also 10 or 20 years from now. We owe that to consumers, to workers, and to industry.**

There are also risks that arise from the structure of the nanotechnology industry itself. Nanotechnology will not play out in a handful of large and well-staffed facilities where oversight and proper workforce training are relatively easy. The scientific investment strategies of the U.S. Government and dozens of other countries have been designed to distribute nanotechnology R&D efforts across hundreds, and eventually thousands, of laboratories globally. These labs will in turn incubate thousands of small firms involved in a Darwinian struggle to push products to market.

Already there are 1,200 nanotech start-ups worldwide, with more than 60 percent in the United States. Added to the university laboratories, we have thousands of people working at the messy and often unpredictable interface between novel technologies and human judgment. Assume that much of the workforce is young—graduate and post-doctoral students, and other Generation-Y types with newly minted science or engineering degrees—a cohort of people that often tend to ignore safety protocols in the workplace.

The government needs "push strategies" directed at small businesses, start-ups, and small labs. If someone is running an 8–10 person nanofirm, we cannot assume they will have significant time and resources to devote to environmental, health, or safety issues. The government (at Federal, State, and local levels) needs to knock on their doors with useful technical and, potentially, financial assistance. Mounting information on government websites will not adequately address this problem.

One of the best ways of delivering this information is to use "intermediaries" such as professional societies along with technical assistance programs at universities and in the extension services of the government. Policy-makers need to constantly ask themselves the question, "Will this program or policy work for small nanotech businesses?" In addition, large companies with the resources to address EH&S issues need to develop strategies to push this know-how down their supply chains to smaller firms involved in nanotech production. Government programs and policies should support and reward such supply-chain approaches in industry.

Small and medium sized firms also need relatively inexpensive and rapid methods to screen emerging nanosubstances and products for human and ecotoxicity. The Federal Government could help by supporting the development of

fast-turnaround, standardized toxicity screens that can fit into the product development cycles of companies. Such screening techniques hopefully would allow environmental and human health problems to be identified early and engineered out of products before they enter the marketplace.

Wildcards

Finally, let me say a few words about what I would characterize as "wildcard" risks such as accidental or intentional releases. Here, I can only comment that I hope we are doing more than I can presently detect. Ed Tenner, a historian of science at Princeton University, once observed that there is a "tendency of advanced technologies to promote self-deception." Nanotechnology is not something we want to get smug or overconfident about. We could be surprised in unpleasant ways, either by the technology itself or by people who mishandle, mislabel, or misuse the technology. Unfortunately, we have no Department of Unintended Consequences in the Federal Government.

An accidental release of engineered nanomaterials into the environment, while probably not posing significant risks, could be a public relations nightmare, with a chilling effect on global investment. For example, the chief executive of a nanotechnology company recently was quoted in the media boasting that his company is manufacturing 50 tons of Polyhedral Oligomeric Silsesquioxanes (POSS ®) chemicals at its supply plant in Mississippi.[17] A patently harmless industrial accident at that facility unrelated to the manufacture of these nano-structured chemicals—first discovered 30 years ago by General Electric Co.—has the potential to create unnecessary public and first responder panic simply because of their association with a technology that is unfamiliar and undefined to most citizens, EH&S professionals, and government safety officials.[18] Planning to address this gap at the federal, State, community, and factory level is essential. I know of no emergency response plans that have been developed by the Federal Government or local first responders to address such a scenario. Such an accident could occur anywhere, which means we need to prepare globally. We need to anticipate, plan for, and rehearse every possible scenario we can imagine, to prepare for think the unthinkable. Of special importance is the consideration of so-called "black swans," events with large impacts, incalculable probabilities, and surprise effects.[19]

In addition, we should assume that bad practices will occur along with good practices as nanotechnology evolves. Everyday, vigilant and intelligent people recognize errors around them and can often come up with ingenious ways to correct problems. Taken one at a time, these bad practices seldom lead to a disaster if recognized early and addressed. The challenge is to develop ways for "error correcting knowledge" to be collected, managed effectively, and channeled into solutions. One model for this is the Aviation Safety Reporting System, which collects and analyzes voluntarily submitted reports from pilots, air traffic controllers, and others involving safety risks and incidents. The reports are used to remedy problems, better understand emerging safety issues, and generally educate people in the aviation industry about safety. A similar system in the U.K., called CHIRP, is designed to promote greater safety in both the aviation and maritime industries and is run by a charitable trust.

We should create a Nano Safety Reporting System where concerned people working with nanotechnologies—in laboratories, companies, or in shipping and transport situations—can share safety issues and concerns. The purpose is not finger pointing but encouraging proactive learning. This information could be used to design educational materials, structure technical assistance programs, and provide a heads-up on a host of possible safety issues. Again, the goal is early warning of emerging risks and the reduction of possible wildcards.

Management and Coordination

Addressing the issues outlined above requires a properly resourced coordination function and smart management.

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[17] Pat Phibbs. "Manufacture of New Carbon Nanotube Approved by EPA Under an Exemption." *Daily Environment.* No. 203, October 21, 2005, page A1.

[18] Robert T. Dixon. "Hybrid Plastics' nanomaterials: From inner molars to outer space," *Small Times.* October 28, 2002.

[19] See: Talib, N. *The Black Swan: Why Don't We Learn that We Don't Learn?,* The United States Department of Defense Highlands Forum papers, February 2004, at: *http://www.fooledbyrandomness.com/blackswan.pdf*

A recent GAO report on results-oriented government makes it clear that effective federal collaboration is key to addressing many 21st century challenges.[20] For the most part, we have yet to develop a winning formula for collaboration. The National Nanotechnology Initiative is one of the most complex interagency endeavors ever undertaken by the U.S. Government, now involving over $1 billion per year in funding and 25 separate agencies. This increase in the number of possible partners across the government leads to an almost exponential increase in the number of possible collaborations—of both productive and potentially nonproductive natures.[21]

The sum of 25 agency missions does not necessarily add up to a coherent federal strategy for addressing risks, engaging the public, providing adequate oversight, or managing the unexpected. It is simply the sum of the missions, or less. As the GAO report points out, these missions are often not mutually reinforcing or can even be in conflict. "You end up with a patchwork of programs that can waste funds, confuse and frustrate program customers, and limit the overall effectiveness of the federal effort."

Our approach to social and ethical issues has largely involved an "outsourcing" model where the scientists do the science and "ethics" are dealt with in separate institutions and centers. Policy considerations have been dealt with as "add-ons" rather than being fully integrated into the research planning process. Given the pace of development, neither one of these approaches is likely to provide government with adequate "early warning" and the necessary lead time to structure effective policies or responses to emerging social and ethical issues.

Nanotechology is just the latest in a series of upheavals in our scientific and industrial landscape, which is being shaped simultaneously by rapid and disruptive changes in areas such as information technology, biotechnology, and cognitive science. Many agencies like FDA and EPA are grappling with the implications of the genomics revolution and are hard-pressed to consider nanotechnologies. These agencies are stretched thin. The depth of expertise in the individual agencies on nanotechnology often involves only 2–3 professionals. Again, most of these people are scientists, not people with public policy or public administration experience.

The managerial and coordination infrastructure in place simply does not match the enormity and importance of the task. **We need a beefed up, visible federal face for nanotechnologies sending a coherent message to the public and industry.** I believe that the National Nanotechnology Coordinating Office (NNCO) can help in this regard, but it is understaffed and under-funded by orders of magnitude. This is not about creating an additional bureaucracy; it is about creating coherence and the capacity to manage a complex enterprise.

Again, let me emphasize that we can succeed with the science but fail on governance, compromising our competitive position.

I hope these observations will be helpful to the Committee as they consider what steps might be taken to ensure that the promise of nanotechnology can be realized.

Key Questions from Different Perspectives

Scientific/Technical

- Which properties or attributes of engineered nanomaterials are particularly significant to health/environmental impacts?
- Are nanomaterials capable of interacting in ways we are currently unaware of, or targeting biological/environmental systems we are unaware of?
- Are there classes of nanomaterials that present a greater or lesser hazard?
- Can we predict chronic/long-term impacts to both humans and ecosystems?
- How will risks change as nanotechnologies evolve (nanobio, nanosystems, systems of systems)? How will we anticipate, evaluate, and manage these risks?
- What are the beneficial applications of nanotechnology to environmental and human health problems? Can nanotechnology be developed so that the benefits outweigh the risks?
- How can we prevent risks posed by the pollution generated in the production of nanomaterials and their associated products?

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[20] General Accountability Office (2005). Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies, GAO–06–15 , October 21, 2005. Summary available at: *http://www.gao.gov/docsearch/abstract.php?rptno=GAO-06-15*

[21] See: Bryan, L. & Joyce, C. (2005). "The 21st Century Organization," *McKinsey Quarterly,* Number 3.

Policy/Regulatory

- What mechanisms work best to regulate nanotechnology-based products?
- Have potential chronic and long-term risks, issues, and consequences been analyzed by policy-makers and government agencies?
- Does sufficient expertise exist in the government to address the EH&S implications of nanotechnology? If not, how will we attract and retain talent?
- What opportunities exist for public-private and international partnerships?
- Will our policies and programs work for small and medium-sized enterprises?
- How can risk management and regulatory models be developed which are relevant to an ever-changing technology?
- How does the structure of the emerging nanotechnology industries affect their response to EH&S issues?
- How have uncertainties and "domains of ignorance" been taken into account during the decision-making, policy-making, and standard-setting process?
- Who will be responsible, and who will be held accountable, for any unforeseen harm, ill-used, or dangerous applications of nanotechnology?
- Who is responsible for collecting data on nanotechnology industries that can inform policy-making (the Bureau of Labor Statistics, the Census Bureau, etc.)?
- Are we trying to anticipate possible accidental misuse of nanotechnologies? Who in the government should be doing this?
- Is there a need for new legislation or a new department specifically focused on nanotechnology?

Public Perception

- Who does the public trust to handle and manage the EH&S risks?
- How is information related to nanotechnology communicated and made available? What media are most effective (for which age groups, for instance)?
- Are public perceptions being included and used to inform debates about proposed and pending regulations?
- How will the public react in the event of an accident, mishap, or product recall? What would the government message be?

BIOGRAPHY FOR DAVID REJESKI

David Rejeski directs the Project on Emerging Nanotechnologies. For the past four years he has been the Director of the Foresight and Governance Project at the Woodrow Wilson Center, an initiative designed to facilitate better long-term thinking and planning in the public sector.

He was recently an adjunct affiliated staff at the RAND Corporation and a Visiting Fellow at Yale University's School of Forestry and Environmental Studies. Before joining the Wilson Center he served as an agency representative (from EPA) to the White House Council on Environmental Quality (CEQ) and, earlier, worked at the White House Office of Science and Technology (OSTP) on a variety of technology and R&D issues, including the development and implementation of the National Environmental Technology Initiative.

Before moving to OSTP, he was head of the Future Studies Unit at the Environmental Protection Agency. He spent four years in Hamburg, Germany, working for the Environmental Agency, Department of Public Health, and Department of Urban Renewal and, in the late 1970's, founded and co-directed a non-profit involved in energy conservation and renewable energy technologies.

He has written extensively on science, technology, and policy issues, in areas ranging from genetics to electronic commerce and pervasive computing and is the co-editor of the recent book *Environmentalism and the Technologies of Tomorrow: Shaping the Next Industrial Revolution,* Island Press, 2004.

He sits on the advisory boards of a number of organizations, including the EPA's Science Advisory Board, the Greening of Industry Network, the Journal of Industrial Ecology, and the University of Michigan's Corporate Environmental Management Program. He is a member of the External Advisory Board of Nanologue, a European project to bring together leading researchers to facilitate an international dialogue on the social, ethical and legal benefits and potential impacts of nanosciences and nanotechnologies. He has graduate degrees in public administration and environmental design from Harvard and Yale.

November 14, 2005

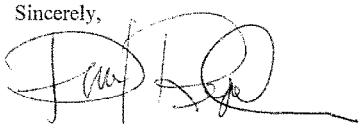
The Honorable Sherwood Boehlert
Chairman, Science Committee
2320 Rayburn Office Building
Washington, DC 20515

Dear Congressman Boehlert:

Thank you for the invitation to testify before the Committee on Science of the U.S. House of Representatives on November 17th for the hearing entitled "***Environmental and Safety Impacts of Nanotechnology: What Research is Needed?***" In accordance with the Rules Governing Testimony, this letter serves as formal notice of the federal funding I currently receive related to the hearing topic.

- $300,000** Cooperative Agreement #82955801-1, United States Environmental Protection Agency/Long Range Planning and Foresight Activities, 2001-2004. **This funding was applied for a range of foresight activities, including genomics, emerging information technologies, environmental modeling, and nanotechnologies. Funding ended last year.

Sincerely,



David Rejeski
Director, Project on Emerging Nanotechnologies and the
Foresight and Governance Project at the
Woodrow Wilson International Center for Scholars
Washington DC

Chairman BOEHLERT. Thank you very much. Dr. Denison.

STATEMENT OF DR. RICHARD A. DENISON, SENIOR SCIENTIST, ENVIRONMENTAL HEALTH PROGRAM, ENVIRONMENTAL DEFENSE, WASHINGTON, D.C.

Dr. DENISON. Thank you, Mr. Chairman, Ranking Member Gordon, and other Members of the Committee. It is a pleasure to be here today.

I share the other witnesses' enthusiasm about the potential benefits that nanotechnology offers society. In my five minutes, however, I would like to make one key point, that federal funding to understand the potential risks of nanomaterials must be greatly increased, and that it is very much in the interest of proponents of this technology that this occur.

I am going to offer you three reasons for why I believe this. First, limited data now available are flashing yellow lights that we

should not ignore. Second, everyone is better off if government takes the lead in developing the infrastructure that will be needed to identify and assess potential risks of nanomaterials. And third, a major federal investment in this area is essential to avoid a public backlash against this promising set of technologies.

Fiscal Year '06 spending directed to risk research amounts to only four percent of the total NNI budget for development of nanotechnology, about $40 million. As detailed in my statement, industry, the insurance and investment communities, as well as environmentalists, are all united in calling for a dramatic increase in this level of funding. It is a truly remarkable convergence, as the Chairman noted at the beginning. We have called for such spending to be increased to at least $100 million annually for at least the next several years. That is about 10 percent of the total NNI budget. And the rationale for that is fully laid out in my written statement, where we have compared to a number of other benchmarks why we think that number is the minimum that is needed.

Two other steps are needed, however, to ensure that the right research is done. First, the NNI, or another federal research agency, needs to be given the responsibility and the authority to develop an overall federal risk research strategy, and to implement that strategy across agencies. And second, we believe Congress should call on the NNI to request the assistance of the National Academies, in particular, the Board on Environmental Studies and Toxicology, in this effort.

Let me now turn to the three arguments I made earlier. First, the flashing yellow lights. Concerns about nanomaterials arise from two sources: first, their novel properties and behavior; and second, some rather surprising results that have occurred in the first studies done. These show that nanomaterials can cross from the lung, when inhaled, directly into the blood. They can even cross from our noses directly into our brains. Some of these particles are able to evade the body's usual mechanisms for defense, and some of them can directly enter cells, where they possibly actually interfere with cellular machinery. While none of these findings directly implicate the harm of these materials, none of them are saying that we should ignore these behaviors and not look any further.

Let me stress that all of the toxicology work that has been done to date has only been short-term in nature. We have no chronic toxicity testing that has looked, for example, at reproductive effects, or at long-term effects like cancer. But even these short-term studies have yielded a number of surprises. For example, when carbon nanotubes are instilled into the lungs of rodents, they consistently have been shown to quickly cause inflammation and also, the presence of unusual cell masses called granulomas. One of these studies actually used a dose that is equivalent to what a worker would get in only several weeks exposure at the current OSHA standard for airborne particles in the workplace. This study also found that fibrosis developed in exposed animals, even in parts of the lung that were far removed from where the particles actually deposited.

Researchers that were developing nanoparticles to target and kill tumor cells also found a rather significant surprise. All 20 of the materials that they developed for this purpose were found to dam-

age other organs: liver, spleen, and kidney, and these effects were only observed because of the extensive testing that is done in the course of drug development to look for adverse side effects. That kind of testing is not routinely required in the vast majority of other applications. In short, there is growing evidence that nanomaterials can get into vital organs and cells, and when they get there, they can do damage.

My second argument. Government needs to develop what I call the enabling infrastructure to address nanomaterials' potential risks. This includes standardizing methods and developing tools to do everything from monitoring of nanomaterials in the environment to understanding how they move through living organisms. Government-funded research is essential to create a database of information about model or representative materials. And none of this is to say that companies don't have the obligation, ultimately, to test their own products prior to commercialization. That is clearly an obligation that remains. But industry needs the infrastructure that I have described in order to do its job.

Last, but not least, my third argument. Failing to make these kinds of investments threatens the future of nanotechnology. We remember genetically modified organisms, where rapid commercialization, coupled with a failure to address the risks up front, led to a public backlash, closed markets, and product bans.

Let me end by saying that nanotechnology offers an enormous opportunity to apply the lessons that we have learned from prior mistakes, identify and take the necessary steps to address the risks up front. In short, we believe there is an opportunity here to get nanotechnology right the first time.

Thank you, and I would be very happy to answer questions.

[The prepared statement of Dr. Denison follows:]

PREPARED STATEMENT OF RICHARD A. DENISON

Summary of Responses to the Committee's Questions

Question 1: Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

- Strong consensus that federal funding for risk research should be substantially increased.

  At least $100 million annually for at least the next several years is needed.

- Needed additional steps:

  NSET or a federal research agency should develop, direct an overall federal research strategy Draw on expertise of National Academies' Board on Environmental Studies and Toxicology.

- Industry should fund research and testing on its products.

Question 2: What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?

- Need for a life cycle view, especially for dispersive applications of nanomaterials.
- Novel properties of nanomaterials that may pose potential risks.

  Potential to cross cell membranes Translocation of inhaled nanoparticles from lung to brain or into systemic circulation.

- Lack of data on chronic toxicity, surprising results in short-term studies.

  Carbon nanotubes (CNTs)

  C60 fullerenes (commonly known as buckyballs)

  Quantum dots

- Importance of surface area and surface properties

  Stability of coatings

Question 3: What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?

- Fundamental need for government to develop or revise tools and methods to:

  Characterize, detect, measure and monitor for nanomaterials

  Assess biological and environmental fate and behavior

  Assess acute and chronic toxicity and ecotoxicity

- Government-led research to create database on representative, model nanomaterials

  Industries using these materials should also help fund this basic work.

- Companies should have responsibility for testing products prior to commercialization.

Question 4: What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?

- Real potential for public backlash if government does not identify, address risks up front.

  As with GMOs, could delay or even prevent realization of potential benefits Public identifies up-front safety testing, more information as critical to building trust.

- Extent of safety assessment conducted could become a competitive issue for U.S. industry.

  Companies indicate they want science-based regulation to provide a more level playing field.

- Public and private interests are best served by identifying potential risks now when they can be avoided, rather than paying later to remediate resulting harms.

I. Introduction[1]

A remarkable and unusual consensus has emerged with respect to the federal government's role in nanotechnology: Organizations as diverse as environmental NGOs, large chemical companies, nanotech startups, insurance companies and investment firms all agree that the Federal Government should be immediately directing many more of the dollars it is currently investing in nanotechnology development toward identifying and assessing the potential risks of nanomaterials to human health and the environment. This federal investment in risk research is essential to developing the basic infrastructure that will enable the private sector to fulfill its responsibility to identify, assess and reduce the potential risks associated with the nanomaterial containing products before they are brought to market.

Nanotechnology, the design and manipulation of materials at the atomic scale, may well revolutionize many of the ways our society manufactures products, produces energy, and treats diseases. Hundreds of large and small nanotechnology companies are developing a wide variety of materials for use in electronics, medical diagnostic tools and therapies, construction materials, personal care products, paints and coatings, environmental cleanup, energy production and conservation, environmental sensors, and many other important applications.

Deliberate exploitation of properties that only become evident at the nanoscale is central to these applications. Such properties include highly specific binding over a huge surface that arises from tiny particle size, absorption and radiation of specific wavelengths of light, penetration of cellular barriers, and high tensile strength and durability. Carefully controlled, these properties may provide highly beneficial products. But these new and enhanced properties also raise the possibility of unintended adverse consequences for human health and the environment. The same binding properties that allow use of nanoparticles to deliver therapeutics to cancer cells may also, for example, deliver toxic substances to normal human cells, or to aquatic organisms if such materials are released or used in the ambient environment. The elec-

[1] A biography of Dr. Denison is attached. Several other Environmental Defense staff contributed to the preparation and content of this testimony: Dr. John Balbus, Health Program Director, Karen Florini, Senior Attorney, and Scott Walsh, Project Manager.

trical properties that drive applications in computers can lead to oxidative damage in living tissues. It is essential that potential harms like these are identified and mitigated up front, prior to widespread commercialization and human and environmental exposure.

II. Responses to the Committee's Questions

This testimony provides Environmental Defense's responses to the four questions posed by the Committee in its invitation letter.

A. Committee Question #1: *Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?*

In our view, current federal and private research efforts are far from adequate to address concerns about environmental and safety impacts of nanotechnology, and funding for such efforts should be substantially increased.

The U.S. Government, as the largest single investor in nanotechnology research and development, needs to spend much more to assess the health and environmental implications of nanotechnology and ensure that the critical research needed to identify potential risks is done expeditiously. Through the National Nanotechnology Initiative (NNI), the Federal Government spends roughly $1 billion annually on nanotechnology research and development. Of this, environmental and health implications research accounted for only $8.5 million (less than one percent) in FY 2004, and is expected to increase to only $38.5 million (less than four percent) in FY 2006.

In a rare example of convergence from sectors that often have highly divergent views, environmentalists, industry and the insurance and investment communities are all calling for dramatic increases in federal funding on the health and environmental implications of nanotechnology. For example, in June 2005 the CEO of DuPont and the President of Environmental Defense co-authored an opinion editorial in *The Wall Street Journal* calling for an increase in such funding to at least $100 million annually. That same month, the American Chemistry Council's Panel on Nanotechnology and Environmental Defense issued a Joint Statement of Principles[2] stating: "A significant increase in government investment in research on the health and environmental implications of nanotechnology is essential." And in a recent report[3] on nanotechnology, Innovest, a leading investment research and advisory firm, has said: "We strongly support calls by others in the investment community for increased government funding of toxicology research. The NNI's lack of priority for this issue represents a missed opportunity to minimize uncertainty."

Similarly, at a briefing held on March 22, 2005, to preview the findings of a report by the President's Council of Advisors on Science and Technology (PCAST) that reviewed the NNI, John H. Marburger III, Science Adviser to the President and chief of the White House Office of Science and Technology Policy, stated that the toxicity studies now underway are "a drop in the bucket compared to what needs to be done."[4]

Our and others' calls for the U.S. government to spend at least $100 million annually on hazard and exposure research for at least the next several years is buttressed by experts' assessments of the cost to conduct the needed research, as well as by testing costs associated with hazard characterization programs for conventional chemicals, and the research budgets for a roughly analogous risk characterization effort on risks of airborne particulate matter.[5] While this level of risk research spending will represent a significant increase over current levels, it is still less than 10 percent of the overall federal budget for nanotechnology development. Moreover, it is a modest investment compared to the benefits of risk avoidance and

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[2] Environmental Defense and American Chemistry Council Nanotechnology Panel, "Joint Statement of Principles," Submitted as Comments on EPA's Notice of a Public Meeting on Nanoscale Materials, 70 FR 24574—Docket OPPT–2004–0122, 23 June 2005, available online at *www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf.*

[3] Innovest (2005). *Nanotechnology: Non-traditional Methods for Valuation of Nanotechnology Producers.* New York, NY. Page 56. Available online at *www.innovestgroup.com/publications.htm* (accessed Nov. 2, 2005).

[4] R. Weiss, "Nanotech Is Booming Biggest in U.S., Report Says," Washington Post, March 28, 2005, p. A6, available online at *www.washingtonpost.com/wp-dyn/articles/A5221-2005Mar27.html.*

[5] A full explication of the basis for the $100 million annual figure, which I submitted earlier this year to the National Research Council's Committee to Review the NNI, is available online at *www.environmentaldefense.org/documents/4446_EnvironmentalDefenseStatement NRCNanopanel25Mar05.pdf*

to the $1 trillion contribution that nanotechnology is projected to make to the world economy by 2015.

What additional steps are necessary? We recognize that at present the NNI's Nanoscale Science, Engineering and Technology Subcommittee (NSET) serves primarily as a facilitator and coordinator of nanotechnology-related activities among the various federal departments and agencies. In our view, ensuring that sufficient and appropriate risk research is carried out by the Federal Government may well require vesting the NSET or one of the lead federal health or environmental research agencies with responsibilities that go beyond these current functions. Sufficient authority to oversee and direct federal risk-related research is essential to ensure first, that the right questions are asked and answered, and second, that identified risks are comprehensively assessed and do not fall through the cracks between statutes, departments and agencies.

We therefore offer two proposals for your consideration. The first is to vest NSET or one of the lead federal health or environmental research agencies with:

- the task of developing an overall federal research strategy for identifying and assessing potential risks of nanomaterials;
- the authority to shape and direct the overall federal risk research agenda across agencies to ensure all critical needs are being addressed, ideally with some budgetary authority; and
- the responsibility to ensure that individual agencies have sufficient dedicated staff and resources to conduct or commission the needed research in their areas, and sufficient authority to identify and assess potential risks.

Our second proposal is that Congress should call on the NNI and its member agencies to request assistance from the National Academies, in particular the Board on Environmental Studies and Toxicology (BEST). BEST should be asked to review the NNI agencies' ongoing research and research plans, offer its guidance on appropriate risk screening and assessment approaches, and help guide the development and implementation of the federal research strategy we call for above, to help ensure the right research is done. BEST has played an analogous role in the formulation and execution of the U.S. Environmental Protection Agency's research strategy for assessing the risks of airborne particulate matter.[6]

Of course, the U.S. Government should not be the sole, or even the principal, funder and conductor of nanomaterial risk research. Other governments are also spending heavily to promote nanotechnology research and development, and they too should allocate some portion of their spending to address nanotechnology risks. And although government risk research has a critical role to play in developing the basic knowledge and methods to characterize and assess the risks of nanomaterials, private industry should fund the majority of the research and testing on the products they are planning to bring to market. Clearly, all parties will benefit if governments and industry coordinate their research to avoid redundancy and optimize efficiency.

B. Committee Question #2: *What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?*

The primary concerns about nanomaterials' health and safety impacts arise both from consideration of the inherent nature and novel properties of at least certain nanomaterials, and from surprising results seen in many of the relatively small number of nanotoxicity studies conducted to date. As described below, various nanomaterials have been demonstrated to have the potential to:

- cross physiological barriers (lung-blood and blood-brain) and enter the systemic circulatory system, thereby posing risks to organ systems removed from the site of entry;
- evade the body's usual metabolic and immune defense mechanisms;
- penetrate cell membranes;
- directly interact and possibly interfere with cellular components;
- deliver secondary molecules to intracellular targets, or reach non-target cells or organs; and

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[6] Board on Environmental Studies and Toxicology, *Research Priorities for Airborne Particulate Matter: I. Immediate Priorities and a Long-Range Research Portfolio,* Committee on Research Priorities for Airborne Particulate Matter, National Research Council, 1998; and *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress,* 2004, both available online at: *books.nap.edu/catalog/6131.html,* and *books.nap.edu/catalog/10957.html.*

- persist and accumulate in the body or the environment.

Scientists are only beginning to examine the extent to which these behaviors can result in significant toxicological impacts, and if so, at what levels of exposure. Likewise, as yet there is little understanding of the mechanisms that lead to the biological effects that have been observed in toxicity studies. Such effects, further described below, include the potential to:

- kill skin cells in culture;
- damage brain tissue in mammals and in fish;
- impair lung function and generate unusual granulomas in the lungs of rodents; and
- kill microorganisms, including ones that may constitute the base of the food web.

Need for a life cycle view, especially for dispersive applications of nanomaterials

Some uses of nanomaterials already on the market, and others now in the pipeline, will result in exposure of humans or the environment, either through direct application or dispersive use. Some of these exposures reflect the inherent nature of the product or application, such as in uses of nanomaterials in drugs and cosmetics, and in remediation of groundwater contamination. Other products may also entail substantial exposures, though not necessarily during a product's use. For example, tennis rackets, automobile running boards, and other products contain carbon nanotubes embedded within resins or other matrices. While exposure to individual nanoparticles during such a product's intended use seems unlikely, a life cycle view is critical to understanding the potential risks. A product's life cycle includes not just the product's use phase, but also its manufacture (and the manufacture of its components) and its disposal or recycling/reclamation. Human or environmental exposures during these other stages may be substantial. For instance, nanomaterials present in cosmetics and sunscreens will be washed off and enter water supplies—as has already been demonstrated for pharmaceuticals and ingredients in personal care products. And although computer users are highly unlikely to inhale carbon nanotubes bound in their computer screen, exposure potential may dramatically increase when recyclers ultimately grind up those screens for other uses. Human exposures are most obvious for the workers doing the grinding, but may also be associated with the various stages of the life cycle of the subsequent product(s)—especially if knowledge of the presence of nanomaterials is not carried downstream along with the material itself.

Novel properties of nanomaterials that may pose potential risks

Potential to cross cell membranes: In some cases, the very properties that make nanomaterials uniquely useful in biomedical or other commercial applications also raise the potential for novel mechanisms and targets of toxicity. For example, the ability of certain nanoparticles to penetrate cell membranes, which new applications to deliver targeted therapies exploit, suggests that nanoparticles will also be able to cross physiologic barriers and enter body compartments that larger particles and smaller molecules do not readily access. Particles of different sizes gain entry into the body's cells via very different mechanisms. Those larger than 500 nanometers (nm) primarily gain entry through active endocytosis; those smaller than 200 nm gain entry through a variety of active and non-active mechanisms.[7] One study of 20-nm polystyrene beads suggests that they enter cells by passing directly through membranes—without requiring specific transport mechanisms. Once inside the cells, these nanoparticles distribute throughout the cytoplasm and appeared to bind to a variety of cell structures.[8]

The manner in which different individual and aggregated nanoparticles may interact with critical cell structures is poorly understood, and cannot be inferred from studies of chemical agents or randomly generated nanoparticles. Surface modifications may allow nanoparticles to bind to cell surface receptors and either avoid uptake[9] or be taken up by specific transport mechanisms, allowing cell targeting for therapeutic agents. It is clear that subtle variations in nanoparticle surfaces, whether due to intentional coating prior to entry into the body or unintentional surface

[7] Rejman, J. et al. 2004. "Size-dependent internalization of particles via the pathways of clathrin- and caveolaemediated endocytosis." *Biochem J.* 377: 159–69.

[8] Edetsberger, M., et al. 2005. "Detection of nanometer-sized particles in living cells using modern fluorescence fluctuation methods." *Biochem. Biophys. Res. Commun.* 332(1): 109–116.

[9] Gupta, A. et al. 2004. "Lactoferrin and ceruloplasmin derivatized superparamagnetic iron oxide nanoparticles for targeting cell surface receptors." *Biomaterials.* 25: 3029–40.

binding or to coating degradation once inside the body, can have dramatic impacts on where and how nanoparticles gain entry into cells, as well as where and how they are transported within cells after entry. Understanding the implications of such transport, as well as ensuring the stability of surface properties throughout the lifespan of manufactured nanoparticles, will be critical to assuring safety.

Preliminary efforts to use nanoparticles for therapeutic interventions indicate that at least some nanomaterials have unanticipated toxic effects—effects that have been detected only because of the testing that routinely occurs in the course of drug development. In one example, researchers developing nanoparticles designed to target gliosarcoma tumor cells noted that, of twenty such materials, all caused adverse effects on the reticular endothelial system (comprised of the liver, spleen and peripheral lymph nodes) and the kidneys.[10]

Translocation of inhaled nanoparticles from lung to brain or into systemic circulation: Nanoparticles can deposit throughout the respiratory tract when inhaled. Some of the particles settle in the nasal passages, where they have been shown to be taken up by the olfactory nerves and carried past the blood-brain barrier directly into brain cells. Smaller nanoparticles have been shown not only to penetrate deeply into the lungs, but to readily cross through lung tissue and enter the systemic circulation. These and other studies suggest that some nanomaterials can evade the lung's normal clearance and defense mechanisms. This potential for rapid and widespread distribution within the body offers promise of a new array of diagnostic and therapeutic applications for these substances—but it also heightens the importance of having a full understanding of their toxicity.

Lack of data on chronic toxicity, surprising results in short-term studies

No studies on reproductive toxicity, immunotoxicity, or chronic health effects such as cancer or developmental toxicity of nanomaterials have yet been published.[11] Of the limited number of short-term studies completed to date, however, several have found a variety of adverse effects associated with each of the major classes of nanomaterials now being produced.

Studies in which **carbon nanotubes (CNTs)** were instilled into the lungs of rodents have consistently demonstrated that CNTs cause unusual localized immune lesions (granulomas) within thirty days, and other signs of lung inflammation.[12,13,14] One of these studies[15]—which utilized lower doses corresponding to the equivalent dose that would be experienced after a few weeks exposure at the current OSHA workplace standard for respirable particles—also found that single-walled CNTs cause dose-dependent fibrosis even in areas of the lung far removed from the sites of particle deposition. One study of multi-walled CNTs showed similar lung toxicity, especially after the material was finely ground.[16] Oxidative stress may be part of the mechanism behind the damage to lung tissue that has been observed in these studies of carbon nanotubes. Single and multi-walled CNTs have also been shown to induce oxidative stress in skin cells.[17,18,19] These studies raise concern for potential toxicity at the beginning or end of the life cycle of products containing CNTs, through workplace exposures or if CNT-containing products undergo weathering, erosion or grinding during recycling or disposal.

C_{60} fullerenes (commonly known as buckyballs) have been less well-studied in mammalian models. A recent study of buckyballs found that, although individual buckyballs do not dissolve well in water, they have a tendency to form aggregates

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[10] Institute of Medicine of the National Academies. 2005. *Implications of nanotechnology for environmental health research.* The National Academic Press. Washington, D.C.

[11] Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies (2005). "Nanotechnology. Environmental and Health Implications. A database of current research." Available at *www.nanotechproject.net.*

[12] Lam, C. et al. 2003. "Pulmonary toxicity of single-wall carbon nanotubes in mice 7 and 90 days after intratracheal instillation." *Toxicol. Sci.* 77: 126–134.

[13] Warheit, D. et al. 2004. "Comparative pulmonary toxicity assessment of single-wall carbon nanotubes in rats." *Toxicol. Sci.* 77: 117–25.

[14] Shvedova, A. et al. 2005. "Unusual inflammatory and fibrogenic pulmonary responses to single-walled carbon nanotubes in mice." *Am. J. Physiol. Lung Cell. Mol. Physiol.* 289(5): L698–708.

[15] Shvedova et al. 2005, *op.cit.*

[16] Muller, J. et al. 2005. "Respiratory toxicity of multi-wall carbon nanotubes." *Toxicol. Appl. Pharmacol.* 207: 221–31.

[17] Monteiro-Riviere, N. et al. 2005. "Multi-walled carbon nanotube interactions with human epidermal keratinocytes." *Toxicol Lett.* 155: 377–384.

[18] Manna, S. et al. 2005. "Single-walled carbon nanotube induces oxidative stress and activates nuclear transcription factor-kb in human keratinocytes." *Nano Lett.* Vol. 5, 9: 1676–1684.

[19] Shvedova, A. et al. 2003. "Exposure to carbon nanotube material: assessment of nanotube cytotoxicity using human keratinocyte cells." *J. Toxicol. Environ. Health A.* 66:1909–1926.

that are both very water-soluble and bacteriocidal, a property that raises strong concerns of ecosystem impacts because bacteria constitute the bottom of the food chain in many ecosystems.[20] They are also capable of being transported via the gills from water to the brains of fish, where they can cause oxidative damage to brain cell membranes.[21] In experiments with human cultured cell lines, buckyballs show high toxicity, causing oxidative damage to cell membranes that leads to cell death.[22]

Quantum dots can be made of a variety of inherently toxic materials, including cadmium and lead. As some of the key applications of quantum dots include diagnostic imaging and medical therapeutics, quantum dots have been studied relatively extensively in biological systems, although only a small portion of this research has focused on potential toxicity. Studies performed to date have mainly been *in vitro* cytotoxicity assays that measure cell damage or death. While results have been somewhat inconsistent, studies that used longer exposure times were more likely to demonstrate significant toxicity.[23] Quantum dots typically have a core made of inorganic elements, but they are generally coated with organic materials such as polyethylene glycol to enhance their biocompatibility or target them to specific organs or cells. Some coatings initially decrease toxicity by one or more orders of magnitude, but the coatings are known to degrade when exposed to air or ultraviolet light, after which toxicity increases. While the presumption has been that this cytotoxicity is caused by leakage of toxic heavy metals (e.g., cadmium or selenium) from the core, there is evidence that some of the molecules used as coatings may have independent toxicity.[24] Significant questions remain about the safety of quantum dots based on the available *in vitro* studies.

Although the doses and methods of administration used in many of these studies do not necessarily reflect mirror likely exposure scenarios, the results strongly suggest the potential for some nanomaterials to pose significant risks.

Importance of surface area and surface properties

Understanding the behavior of nanoparticles requires careful characterization of their surface properties. For a given mass of particles, surface area increases exponentially with decreasing diameter (and increasing number). This increased surface-area-to-volume ratio may be a critical feature in understanding the toxicity of nanomaterials. For example, it leads to higher particle surface energy, which may translate into higher reactivity.[25] In addition, the combination of high surface area and small size may give nanoparticles unusual catalytic reactivity due to quantum effects, such as those seen with gold nanoparticles.[26] This combination of enhanced surface area and enhanced surface activity lends far greater complexity to the characterization of nanoparticles, and also precludes easy extrapolation about potential toxicity.

Stability of coatings: Most research to date has used prototypical or "plain" nanoparticles, such as uncoated buckyballs and carbon nanotubes. The few studies that have looked at the effects of variations and coatings have shown that these changes modify (typically reduce) the toxicity of the original particle, further complicating the picture by raising the question of how these coatings may degrade over time within the body or in the environment.

In sum, the limited information available to date indicates that nanomaterials can both: a) exhibit novel properties and behavior that facilitate access to organisms, including specific cells or organs, raising the potential for biologically significant exposures to occur should such materials be released, and b) exhibit toxicity to a range of cell and organ types both *in vitro* and *in vivo.*

C. Committee Question #3: *What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?*

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[20] Fortner, J. et al. 2005. "C60 in water: nanocrystal formation and microbial response." *Environ. Sci. Technol.* 39: 4307–16.

[21] Oberdörster, E. 2004. "Manufactured nanomaterials (fullerenes, C60) induce oxidative stress in the brain of juvenile largemouth bass." *Environ. Health Perspect.* 112: 1058–62.

[22] Sayes, C. et al. 2004. "The differential cytotoxicity of water-soluble fullerenes." *Am. Chem. Soc.* 4: 1881–1887.

[23] Hardman, R. 2005. "A toxicological review of quantum dots: toxicity depends on physicochemical and environmental factors." *Environ. Health Persp.* Nat. Inst. of Environ. Health Sci. doi: 10.1289/ehp.8284. Available at: *http://dx.doi.org.* (Accessed on November 4, 2005).

[24] Hardman et al. 2004, *op. cit.*

[25] Oberdörster, G. et al. 2005. "Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy." *Part. Fibre Toxicol.* 2: 8.

[26] Daniel, M. et al. 2004. "Gold nanoparticles: assembly, supramolecular chemistry, quantum-size-related properties, and applications toward biology, catalysis, and nanotechnology." *Chem. Rev.* 104: 293–346.

There is broad agreement among stakeholders that addressing the potential risks of nanotechnology will be an unusually complex task. Despite its name, nanotechnology is anything but *singular;* it is a potentially limitless collection of technologies and associated materials. The sheer diversity of potential materials and applications—which is a source of nanotechnology's enormous promise—also poses major challenges with respect to characterizing potential risks.

Even before the research that will allow hazards and exposures to be quantified, a number of more fundamental needs must be addressed. It is already clear that even extremely subtle manipulations of a nanomaterial can dramatically alter its properties and behavior: Tiny differences in the diameters of otherwise identical quantum dots can alter the wavelength of the light they fluoresce; slight changes in the degree of twist in a carbon nanotube can affect its electrical transmission properties. A priority must be to develop the means to sufficiently characterize nanomaterials and to systematically describe and detect such subtle structural variations—a clear prerequisite to being able to conduct and interpret the results of toxicological testing and exposure measurements. Emphasis needs to be placed, therefore, on developing methods, protocols and tools needed to *characterize* nanomaterials, and to *detect and measure* their presence in a variety of settings (e.g., workplace environment, human body, environmental media).

Among the types of risk research that are needed for specific nanomaterials are the following:

- Material characterization (in manufactured form(s), during use, in emissions, in wastes, in products; in environmental media, in organisms)
- Biological fate (extent and rate of absorption, distribution, metabolism, elimination in mammals and other organisms)
- Environmental fate and behavior (persistence, transport between and distribution among media, transformation, bioaccumulation potential)
- Acute and chronic toxicity (related to both human and ecological health)

For each of these areas, existing testing and assessment methods and protocols need to be re-examined to determine the extent to which they can be modified to account for nanomaterials' novel characteristics or need to be supplemented with new methods. Similar challenges will arise with respect to methods and technologies for sampling, analysis and monitoring, all of which will be needed to detect nanomaterials and their transformation products in living systems and in various environmental media.

Another essential task for government-funded research is helping to create an initial database of toxicity data on representative or model nanomaterials. Doing so will help guide additional research by the private sector on their own nanomaterials, and will also lay the groundwork for the ultimate development of so-called "structure-activity relationships" (SARs) for nanomaterials. SARs are now widely used to reduce the amount of traditional toxicological testing needed to characterize conventional chemicals, by allowing the toxicity of an unstudied chemical to be estimated, based on its degree of structural similarity to chemicals that have been studied. Use of SARs is beneficial for several reasons: it's faster, it's cheaper, and it can minimize the need for testing using laboratory animals. But existing SAR models cannot simply be applied to nanomaterials: Because the models are based on the properties of bulk forms of conventional chemical substances, and because nanomaterials' novel and enhanced properties result from characteristics (e.g., size, shape) in addition to their molecular structure, existing models have little applicability to nanomaterials. In other words, the defining character of nanotechnology—the emergence of *novel* properties and behavior that cannot be predicted from the properties and behavior of their bulk counterparts—effectively precludes our relying on existing knowledge about the toxicity of conventional chemicals to predict the toxicity of nanomaterials. Only once enough data exist to correlate a nanomaterial's properties—or the changes in such properties that occur in the body or the environment—with observed patterns of toxicity, will nanomaterial-specific SARs be possible.

In sum, government needs to play the lead role in developing the *enabling infrastructure* for identifying and assessing nanomaterials' potential risks, including by developing and standardizing methods for:

- physical-chemical characterization of nanomaterials;
- sampling and analysis;
- detection and monitoring: in workplaces, air/waterborne releases, humans and other organisms, environmental media;
- assessing environmental fate and behavior;

- assessing biological fate and behavior, including generating and making available radiolabeled or otherwise traceable samples of key types of nanomaterials, for government's own and others' use in such fate studies;
- testing for acute and chronic toxicity, including the development and validation of non-animal test methods where doing so is scientifically appropriate, in order to minimize animal testing; and
- hazard, exposure and risk assessment.

As noted above, given its major investment in nanomaterials development, it is also appropriate for government to identify and conduct a full characterization and testing of a variety of "model" nanomaterials, although industries already using these materials should also help fund this basic work. Government should also take the lead on coordinating the efforts of private and public sectors, and for international cooperation and coordination of risk research.

None of the above should be construed, however, as a substitute for companies taking responsibility for (and bearing the financial burden of) all of the testing needed to ensure the safety of their products prior to commercialization. To ensure maximum value and bolster public confidence in such research, we believe government and industry should commit to make publicly available *all* results, not just "interesting" ones that may be publishable in scientific journals or are required by law to be reported.

D. Committee Question #4: *What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?*

While industry representatives may be in a better position to fully address this question, let me discuss one type of impact—public backlash—that could readily arise, given the growing evidence of potential health and environmental risks posed by certain nanomaterials, and the government's to-date-inadequate effort to identify and address such risks. The "risks" at issue here, therefore, are not only those related to health and the environment, but also risks to the very success of this promising set of technologies. If the public is not convinced that nanomaterials are being developed in a way that identifies and minimizes negative consequences to human health and the environment, a backlash could develop that delays, reduces, or even prevents the realization of many of the potential benefits of nanotechnology. As demonstrated with genetically modified organisms just a few years ago, rapid commercialization combined with a failure to address risks early on can lead to product bans and closed markets, resulting in this case in hundreds of millions of dollars in annual export losses for U.S. farmers and companies.

While little research into public attitudes toward nanotechnology has been conducted to date, some recently reported findings[27] are telling. In the context of finding generally low public awareness of nanotechnology and, among those with some awareness, a generally positive attitude, there were also some warning signs:

- Public trust in government appears to be low, with no more than half of the surveyed members of the public expressing confidence in Congress' or the Executive Branch's willingness or ability to manage nanotechnology-related risks.
- Suspicions of industry abound, with only a small percentage indicating that industry could be trusted to "self-regulate" and a concern that industry often rushes products to market without adequate testing.

Equally interesting were the responses concerning how the government and industry might best build public trust. For example:

- The two best ways identified by respondents to build public trust were requiring increased safety testing prior to introduction of products onto the market, and provision of more information to inform consumers' choices. Better tracking of risks for materials already on the market also ranked high.
- The lack of information on long-term health and environmental effects of nanotechnology and its products was frequently cited as a major concern.

Of course, all of these findings stress the need for more and better research into potential short- and long-term risks to be conducted now, prior to widespread commercialization of nanomaterial-containing products.

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[27] Woodrow Wilson International Center for Scholars, "Informed Public Perceptions of Nanotechnology and Trust in Government," authored by Dr. Jane Macoubrie, Washington, DC, September 2005, available online at *www.wilsoncenter.org/news/docs/macoubriereport1.pdf*.

Finally, there is growing reason to expect that the extent of safety assessment conducted prior to market introduction of nanomaterial-containing products could well become a competitive issue. The investment firm Innovest notes in its recent report:

> "Off the record conversations with regulators indicate that Europe, the UK, and China are expecting to have some sort of binding requirement for companies within the next two to four years. China clearly states that its standards were designed to create a robust foundation for nanotechnology development in that region and that they expect their standards to impact the competitive landscape for nanotechnology." [28]

Clearly, the U.S. nanotechnology industry will benefit from an environment in which it can offer reassurances that the safety of its products has been assessed using robust methods and evaluation procedures. Industry itself recognizes as much; as the Innovest report goes on to note:

> "A significant portion of the more than 60 companies we interviewed indicated an interest in having some sort of standards in place. In many cases, they felt that science-based regulation would provide a more level playing field. The lack of adequate funding for toxicology research is, again, an issue here.. . .Counter to intuition, our research shows that robust, science-based regulation can contribute to healthy market development."

III. Conclusion

In our view, both the public and private sectors' best interests are served by an investment to identify and manage potential nanotechnology risks now, rather than to pay later to remediate resulting harms. History demonstrates that embracing a technology without a careful assessment and control of its risks can be extremely costly from both human and financial perspectives. The failure to sufficiently consider the adverse effects of using lead in paint, plumbing, and gasoline has resulted in widespread health problems that continue to this day, not to mention extremely high remediation costs. Asbestos is another example where enormous sums of money were spent by private companies for remediation, litigation, and compensation, even beyond that spent by the public sector to alleviate harm to human health and the environment. Standard & Poor's has estimated that the total cost of liability for asbestos-related losses could reach $200 billion.[29]

The rapid commercialization of nanotechnology, coupled with the potential risks from at least certain nanomaterials as demonstrated in initial studies, lends urgency to the call for greater investment in risk research from the outset. Government and industry have done a great job so far in accentuating nanotechnology's potential upsides and in accelerating its development, but they have yet to come to terms with their equally critical roles in identifying and avoiding the downsides. A far better balance between these two roles must be struck if nanotechnology is to deliver on its promise without delivering unintended adverse consequences.

Fortunately, nanotechnology development and commercialization is still at an early stage, so it is not too late to begin managing this process wisely. Given the length of time it will take to develop an adequate understanding of the potential risks posed by such a wide variety of nanomaterials, and to apply this knowledge to inform appropriate regulation, it is imperative to take action now.

Nanotechnology offers an important opportunity to apply the lessons from prior mistakes by identifying risks up front, taking the necessary steps to address them, and meaningfully engaging stakeholders to help shape this technology's trajectory. In short, there is an opportunity to get nanotechnology right the first time.

BIOGRAPHY FOR RICHARD A. DENISON

Dr. Denison is a Senior Scientist in Environmental Defense's Environmental Health Program, working in its Washington, D.C. office. He specializes in hazard and risk assessment and management for industrial chemicals (including nanomaterials), and associated policy and regulatory issues. Dr. Denison is a member of USEPA's Pollution Prevention and Toxics Advisory Committee (NPPTAC), including its Workgroup on Nanotechnology, and serves on the Steering Group for Nanotechnology of the Organization for Economic Cooperation and Development (OECD).

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[28] Innovest (2005), *op. cit.*

[29] Standard & Poor's, *Insurance: Property-Casualty Industry Survey,* July 15, 2004.

Dr. Denison manages Environmental Defense's participation in the U.S. High Production Volume (HPV) Chemical Challenge Program, initiated by Environmental Defense, EPA and the American Chemistry Council to provide basic hazard data on the 2,200 chemicals produced in the U.S. in the largest quantities. He also represents Environmental Defense in proceedings of the Chemicals Committee and the Existing Chemicals Task Force of the OECD. He has authored several papers and reports, and is active in a variety of activities and fora, pertaining to nanomaterials and chemicals regulation and policy at the federal and State levels and internationally.

Dr. Denison earned a Ph.D. in Molecular Biophysics and Biochemistry from Yale University in 1982. He joined Environmental Defense in 1987, after several years as an analyst and assistant project director in the Oceans and Environment Program, Office of Technology Assessment, United States Congress.

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November 14, 2005

The Honorable Sherwood Boehlert
Chairman, Science Committee
2320 Rayburn Office Building
Washington, DC 20515

Dear Congressman Boehlert:

Thank you for the invitation to testify before the Committee on Science of the U.S. House of Representatives on November 17th, 2005, for the hearing entitled "***Environmental and Safety Impacts of Nanotechnology: What Research is Needed?***." In accordance with the Rules Governing Testimony, this letter serves as formal notice that I received no federal funding directly supporting the subject matter on which I will testify, in the current fiscal year or either of the two preceding fiscal years.

However, via contract from the Woodrow Wilson International Center for Scholars, Environmental Defense's Alliances Program did receive $10,000 to prepare a Nanotechnology White Paper in FY05 (completed). The Wilson Center's funds came from EPA.

Sincerely,

Richard A. Denison, Ph.D.
Senior Scientist

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DISCUSSION

Chairman BOEHLERT. Thank you very much, Dr. Denison. Thanks to all of you for your informed testimony, and we are considering that, along with input from a number of other sources, as we deliberate.

Mr. Nordan, I couldn't agree more with your statement. You said U.S. must not be left behind in this enterprise. Where are we now? I mean, you know, we always, when you are looking around the world, you want to see what the competition is doing. Where are we now? Are we ahead? And are we running the risk of falling behind? Give me your assessment.

Mr. NORDAN. We authored a report earlier this year on this topic, and we tried to rank 14 nations globally on two things, on the level of nanotechnology activity in the country, say how many papers being authored, startups being generated, et cetera, on an absolute scale, and then secondly, on the track record of the country in being able to convert science and technology innovation into inward investment and GDP growth and jobs.

On those two metrics, the U.S. actually comes out on the top on nanotechnology activity globally, and comes out near the top on technology development strength. So, we would put the U.S. in the first position in the world today when it comes to nanotech commercialization. That said, there are other countries that are catching up very rapidly, China being a great example, which has gone from the world's fifth to second in nanotechnology publication in about 10 years, and which at this point spends, at purchasing power parity, when you correct for how far a unit of currency goes in a country, second only to the United States on nanotechnology research.

Now, what is unique, actually, about a month ago, had the opportunity to do onsite visits on the ground to 15 nanotechnology startups and research labs in mainland China, in Shenzhen, Beijing, and Shanghai, and what you find there, compared with the U.S., is that nanoparticles used in things like coatings and composite materials are far more advanced in terms of commercialization than in the United States. It is very typical to be able to go to a building supply store through a retailer, and find paints that contain nanoparticles, or plastic materials that contain nanoparticles in China, that are somewhat absent in the U.S.

Now, some of the reason for that is that there has been a very big focus on specifically these nanoparticles. Some of it is that the Chinese institutions don't have the same EHS strictures that exist in the U.S. That does not mean, in any way, that we should relax one iota the amount of rigor we approach EHS issues with in the United States, but it does mean that we have to supply a base of data and eliminate regulatory ambiguity rapidly in order to keep up.

Chairman BOEHLERT. Thank you very much. That was a very good thumbnail sketch. One of the things that always concerns us as policy-makers is that we have come to the realization we don't know what we don't know, and so, given the large gaps of knowledge—this is a broad question that I would like all the panelists to address—given the large gaps in knowledge that may take many

years to fill, how should we ensure protection of public health and the environment in the interim? I mean, what immediate steps do we need to take? Dr. Teague.

Dr. TEAGUE. Well, first of all, I would like to say that we have recognized exactly what you said within the Federal Government, and particularly, within the regulatory agencies, and that is the reason that it has been stepping forward, to put into place interim measures until we do learn more. The document that I mentioned from the National Institute of Occupational Safety and Health is put forward as a preliminary document, based upon what we do know now, to try to encourage everyone to take appropriate measures about the lack of knowledge that we have about the potential risks associated with nanoscale particles. It has been widely and enthusiastically accepted by almost everyone that we have introduced it to, including at the International Standards Organization meeting, that I attended just last week. All countries saw it as a major step forward to have this document available, to protect as best we know, people in the workplace.

If you go to the website, it is there, available for anyone, including small manufacturers, anyone can get access to the document readily. It is also stated that it is a preliminary document, and that as more is learned, it will be updated. If you also go to the websites of the Food and Drug Administration, the Consumer Product Safety Commission, and other of the regulatory agencies, they have put forward what we have called their agency position statements about how they will interpret their regulatory authorities with respect to these particles. All are stating that currently, within the available regulatory authorities, they see full capabilities for preventing any adverse effects on public health or the environment, as we now understand it.

Chairman BOEHLERT. Thank you very much. Anyone else care to comment on that one? Dr. Denison.

Dr. DENISON. Thank you, Mr. Chairman. We have advocated for a number of interim steps, as the data are developed, to look at the actual risks. One is that in the context of workplace safety, we believe that companies would be prudent if they looked at examining and monitoring of the health of workers that are potentially exposed to this, for example, so that we develop a baseline, and we have, over the course of time, the ability to know whether an effect is happening that we don't maybe understand yet. Second, materials in the workplaces really should be being handled in a way, in the absence of data to the contrary, that is basically as if they were hazardous materials. In other words, we would be doing everything we could to eliminate the possibility of exposure occurring, unless we know that that exposure is safe.

And thirdly, we are very concerned about the subcategory of applications of nanomaterials that are dispersive in nature, that is, they deliberately or as a result of the use of a product, disperse materials into the environment. In the absence of data that indicates that that dispersion is actually harmless, we think those uses really ought to be looked at very, very carefully, and probably avoided or slowed down until the data generation catches up.

Chairman BOEHLERT. Thank you very much, and I would like to go on, but seeing the Committee interest here, and my red light is on, and something compelling, Mr. Rejeski?

Mr. REJESKI. Yeah, I would just add to this, I mean, every week, we get calls from small and medium-sized companies. You have to realize that the nanotech industry is going to be dominated by small startup firms, and they are asking the right questions, and they cannot find the information. So, I think it is interesting to put this guidance out, but if a company can't find it within two mouse clicks of their computer, you have lost them. So that, essentially, the government has got to be able to develop a portfolio of push strategies to get to these companies. Using our extension services, using technical assistance programs at universities, because they just don't have the time. Essentially, they are in a kind of Darwinian struggle to get their product to market. So, again, they are asking the right questions. They have a real hard time finding the right answers. So, I think we need to think about how do we reach those people.

Chairman BOEHLERT. Thank you. Now, that is constructive, and I do appreciate that. It is a popular sport around the country to be critical of government, but you know, we do most things right, quite frankly, and every time I fly in a plane, you know, I am so thankful that we have got the FAA. Every time I go to the pharmacy to get a prescription filled, I am so thankful that we have got the Food and Drug Administration. But the point is, we can always find ways to do things better, to be more immediately responsive to an identified national need, and that is the whole purpose of this hearing, and the work we are about. So, the constructive comments you have offered are not going unnoticed, and we intend to pursue that, but I want to pursue my colleagues on the committee, and be mindful of their interests, so with that, my time has expired. Mr. Gordon.

Mr. GORDON. Thank you, Mr. Chairman. As the Chairman pointed out, we do have time limitations, so I want to try to address some of these issues cumulatively here, or jointly, with all of you.

Do any of the witnesses not agree that the current funding level under the National Nanotechnology Initiative is inadequate for supporting the environment, health, and safety research? Does anyone not agree with that?

Do you want to disagree with that, that you think we are spending enough?

Dr. TEAGUE. Well, let me clarify the amount that is being expended, if I may.

Mr. GORDON. Well, I prefer, let us get some base information, then we can go to that. So, do you disagree that we are not spending enough?

Dr. TEAGUE. I think that the amount that is being spent currently——

Mr. GORDON. Is adequate?

Dr. TEAGUE.—is certainly within the amount that we have——

Mr. GORDON. Well, I am not trying to be argumentative——

Dr. TEAGUE. Yes.

Mr. GORDON. I just want to try to get through some questions, then we can talk about it.

Dr. TEAGUE. Okay.

Mr. GORDON. Okay, do you think that we are spending enough on the research for the health aspects of nanotechnology?

Dr. TEAGUE. Considering all that goes into that number, and the supporting amount, I guess I would say yes.

Mr. GORDON. Okay. You think we are spending enough. Okay. Does anybody agree with him that we are? Okay. So, just for the record, I guess you are saying that you are a company man, and that the company is doing all right. So, the rest don't seem to agree. Now, some of the witnesses suggest that the current level should be at least $100 million. Others have had other levels. And I would assume, Mr. Teague, you would think that $100 million is too much to spend. So, let me ask, do the rest of the witnesses think that it would be a good level, or could you spend less than that? Does anybody think that it should be less than $100 million? Yes, sir.

Mr. REJESKI. I don't think we can actually answer that question. I could tell you right now that based on the preliminary analysis we have done, we have got $23 million of federal funding in our database. We have got 154 projects across eight agencies. That is not everything, but we have looked at it, and we have found some areas where we think the government is doing, actually, a fairly good job, and they should be congratulated. We have found some zeros. We have found some really large gaps. We don't think there is enough being spent on safety issues, explosion hazards, that sort of thing, that could be caused by nanomaterials in the workplace. So I think, again, I hate to base the argument on just broad numbers, because I think we really need to sort of dive deep into the actual funding levels, and I think that is what is going to help us.

Mr. GORDON. Well, that goes back to your original testimony. I know you are reinforcing that, but I am just trying to get some benchmarks. So, don't know whether $100 million——

Mr. REJESKI. I don't know.

Mr. GORDON.—would be a good place? Okay. So——

Mr. REJESKI. I don't know. I can't tell you that.

Mr. GORDON.—we have got one no, and we have got one don't know, and I think in the rest of your testimony, you said either $100 million or more. Is that correct? Okay. Again, I am just trying to get some benchmarks here.

Dr. TEAGUE. May I comment, sir?

Mr. GORDON. Yes, sir. Certainly.

Dr. TEAGUE. In your question to me the last time, I didn't fill out my comments that I would like to say relative to whether or not it is the right amount of money. Very much, I agree with what Mr. Rejeski just said, but I emphasized in my opening remarks that the amount of money that is being invested in EHS implications research. It is stated as the research and development whose primary purpose is to investigate environmental, health, and safety implications. So, all of the funding——

Mr. GORDON. Okay. Again, I have got a limited amount of time. I am not questioning whether you are doing the best you can with the resources you have. I am not questioning you in any way. I am just trying to determine whether we should do more. That is what I mean. So, let me ask the witnesses as a whole this. If no new

money were available for research in this area, would you recommend reprogramming some of the existing funds in the National Nanotechnology Initiative? Does anyone not agree with reprogramming, if there would not be additional funds available? Would you just raise your hand, and we will let you say something about that?

Mr. NORDAN. I think the point that I would make, to go back to Mr. Rejeski's comments, is that a pretty fine-grained understanding of what the gaps are, and down to the level of specific materials and specific projects would be required. That said, there are some places that jump out as fairly significant holes. The biggest one that we have identified is the risk of nanoparticles that are——

Mr. GORDON. But I guess what I am trying to say is—what I am trying to get a calibration here, is these are difficult times to——

Mr. NORDAN. Yes.

Mr. GORDON.—try to get additional funds, and so, it is unlikely we are going to see any. Matter of fact, nanotechnology has been treated very generously, in terms of the rest of the budget. Now, we would like to see more, but in a relative term, it has been, you know, very generous. And so, I don't think we are going to get a lot of additional funds. Is this—is the concern about additional research into safety enough that you would recommend reprogramming existing funds to do that?

Mr. NORDAN. Definitely one option. There are also other options.

Mr. GORDON. Please, I know that, but that is the option I am talking about right now.

Mr. NORDAN. I think that would be feasible.

Mr. GORDON. Okay. Is there anyone who would not, because Mr. Ehlers is trying to push the button on me here. Is there anyone here who would not agree that it is enough of a problem, or a concern, that if we can't additional funds, that we should reprogram funds? Would anybody disagree with that statement? Raise your hand. Okay, go right ahead, Mr. Teague.

Dr. TEAGUE. If I look at the agencies which are currently funding the work on research for environmental, health, and safety implications, they are within the National Science Foundation, they are within the National Institute of Occupational Safety and Health. They are within other components of HHS or the National Institutes of Health. So if you are saying that you need to increase, let us say, the amount of funding that would be available to the National Institute of Environmental Health Sciences.

Mr. GORDON. Well, I said within the National Nanotechnology Initiative.

Dr. TEAGUE. They are one of the agencies that is contributing to the NNI.

Mr. GORDON. Yeah.

Dr. TEAGUE. A very significant one. Then, where would you pull it? Would you pull it from the other parts of NIH that are investing in cancer research?

Mr. GORDON. That is one question I would be asking you, but if we are trying to establish priorities, it would be most likely from funds that are allocated for nanotechnology research.

Dr. TEAGUE. Some of those, we——

Mr. GORDON. And that would be some reprogramming there.

Dr. TEAGUE. Some of those which are investigating new treatments and new methods of diagnosing cancer.

Mr. GORDON. Well, if you want to put it in the most harsh way, that is the question I am asking you. You know, would it be enough of a priority to slow down that cancer research to make sure that it was being done in an appropriate way, and that is the question I am asking you, and you are saying what? No.

Dr. TEAGUE. I am saying no at the present time.

Mr. GORDON. And you wouldn't. Okay, but everyone is saying yes, is that true? Is that correct?

Dr. DENISON. Could I offer just one comment on this? I think there are two types of reprogramming. One is to take money from the application side and move it to the implication side, which you have been talking about. Even within the implications research, though, there are some rather striking things. Almost two-thirds of that money that is devoted to EHS research is in the National Science Foundation, which is probably not where I would suggest that much of that amount of money ought to be put. The agencies that have, as a prime mission, understanding health and environmental implications have a much, much smaller piece of that pie.

Mr. GORDON. Well, again, we don't live in a perfect world. We have to deal within these circumstances that we have, and that is what I am trying to get from you, those kind of priorities. Excuse me. Thank you, Mr. Ehlers.

Mr. EHLERS. [Presiding] Indeed, we don't live in a perfect world, so I will have to declare the gentleman's time has expired. I apologize for being late. I was detained in another meeting, but I would, without objection, enter my statement in the record. So ordered.

The normal procedure in this committee is that the Chair and the Ranking Member ask questions, then the Chairs of the relevant subcommittees and their Ranking Members ask questions, and then we go to the rest, but I have a special request, and I am next in line, and after that, Mr. Wu, Mr. Inglis, and Ms. Hooley, if she arrives. But if none of those four object, I would like to recognize Mr. Gutknecht, who has a burning question he wishes to ask, and has to depart for another meeting.

Mr. GUTKNECHT. Mr. Chairman.

Mr. EHLERS. I hear no objection, so I recognize the gentleman from Minnesota.

Mr. GUTKNECHT. Mr. Chairman, I don't know how burning it is, but I do have to leave, and I was among the first people here. And so, I will jump in line.

Mr. Nordan, you raised the issue, and I have a very keen interest. On the Agriculture Committee, we have had this ongoing, and you brought up the issue, but we have had this ongoing fight over biotechnology and what it really means, and I have often said that the pharmaceutical companies and the seed companies who develop these technologies have done a marvelous job of selling the technology to our farmers. They have done a miserable job of explaining it to the consumer, and as a result, we continue to have this battle, not only in Europe, principally in Europe, but even here in the United States.

I guess I would like to have you perhaps develop this thought. What responsibility does industry have to do a better job not only

of explaining the benefits of this new nanotechnology to potential industrial or commercial users, but more importantly, of explaining what this all means to the consumers and private individuals? So, perhaps you could talk about that, and if anybody else wants to talk about it, because I am really worried that we are going to go down the same path with biotech corn and cotton and beans and so forth.

Mr. NORDAN. I would argue that is happening today. Let me talk a bit about the situation, and then talk about the challenge.

The situation is a little puzzling. When it comes to real risks, they are somewhat bounded. Right. The field of nanoparticles is extremely broad, involving ceramic nanoparticles, metal nanoparticles, carbon-based ones, some of which are just smaller version of existing structures, some of which are unique structures that only form at the nanoscale, and if one of those proves to pose an environmental, health, and safety risk, there are boundaries around it. It doesn't necessarily apply to all the different forms.

When it comes to perceptual risks, though, it kind of only takes one bad apple to spoil the bunch, in terms of public perception. So, it is a significantly challenging situation, and it is more challenging than biotech, because it is fairly straightforward to put some boundaries around what constitutes biotechnology, manipulating genes in order to achieve desired effects in living organisms. Nanotechnology applications are so diverse, ranging from structural materials to cancer treatments to energy sources, that it is very difficult to encapsulate them in a sentence or two phrase that is easy to understand.

Given the importance and the primacy of perceptual risks in getting consumer adoption of products based on these technologies, it comes as something of a shock to us that for the most part, industry and specifically startup companies have done exceedingly little to engage the public on these topics. In fact, when it comes to startup companies, there are many cases where they would seem to be avoiding raising the issue, because anything that could possibly scare away venture capitalists, or keep them from being able to attain a next funding round is a topic to address behind the scenes, but not something they want to raise publicly, which we believe in the long-term is very self-destructive. There are some companies out there, like BASF in Germany and like DuPont in the United States, that have done an exceptional job of partnering publicly and communicating publicly about these issues, but that is the exception to the rule, and it is something that from a business perspective, is a self-inflicted wound in the long-term.

Mr. GUTKNECHT. What can we do about that? Because I share your concern, and that is why I raise the point. And I think we are going to get a long ways down this road before many in industry really understand how serious this is.

Mr. NORDAN. Yeah, there are folks on the panel that have more experience than I do in public engagement with consumers on new technologies, so I would turn to Dr. Doraiswamy and Mr. Rejeski and Dr. Denison for that.

Mr. GUTKNECHT. Thank you.

Dr. DORAISWAMY. Thank you. I think the question that you raise is a very good one, and a very appropriate one. We believe that in

order to ensure that there is no miscommunication or misunderstanding of what nanotechnology is and what it can deliver, we do need a more effective process for communication and outreach, more transparency in this area than maybe people have been accustomed to, and more collaboration among all of the stakeholders.

As an example of the kind of confusion that exists, most of the concerns and questions that we have been discussing today about safety, health, and environmental implications are, in fact, confined to nanoparticles. The fact is that the word nanotechnology is much more broadly applied to other kinds of materials that do not involve nanoparticles, for example, nanostructured membranes that might have pores, for example, that are nanosized and could be used in applications like protecting against chemical and biological threats. These are materials that have very different characteristics from nanoparticles, but if we put them all under the same umbrella, there is a tendency to confuse them and what the implications might be.

So, in order to resolve some of this confusion, I think we do need a more consistent vocabulary, and the standards organizations, I think, are working on that. We do need, I don't think any one company alone can address the confusion. I do think we need a coordinated effort to identify where the confusion is likely to arise, to structure the space and partition it appropriately, and address our communications to where there is the greatest possibility for miscommunication.

Mr. GUTKNECHT. Anyone else? Yeah, please.

Mr. REJESKI. I think one of the things that was striking as we went around and ran focus groups around the country, and talked to people about nanotech is that the public, the people were very, they didn't focus a lot on the thing, whether it was the gadget, the golf ball, the cosmetics. They were asking, and they really wanted answers to a much larger set of contextual questions. They were saying before we trust anybody, we want to know who is developing this, who is promoting it? Is this being hyped? And then they want a balanced message. They are not afraid of hearing bad news. They don't expect a no-risk society. They want to know who is evaluating it, and they want to know if something goes wrong, who is responsible? And that is why I think essentially reducing perceptual risks has an awful lot to do with the government's message, because the government is really quite often responsible for doing a lot of this. They ask about can we trust the FDA, the EPA, what are these people doing? So, I think it really says, a balanced message, they don't want to be hyped with this stuff. They want to hear from the government, in terms of the context. Are we creating a context that they can believe in, that they trust the risk managers, essentially.

Mr. GUTKNECHT. But how would you respond? I mean, the USDA and lots of other government scientists have released reports about biotechnology used in plants. There has never been a study that indicated there was any health risk whatsoever, and yet there is still this great perception out there that there is a risk.

Mr. REJESKI. Well, I think a lot of that has to do with the fact that we also aren't engaging effectively with a lot of the people that are shaping that perception. So that means, I think, a much better,

you know, sort of outreach strategy with the media, with the non-governmental organizations, essentially they got ahead of us on that message. And I think the same thing can happen here. I think right now, we have a small window of opportunity, now, I think it is about a year where we can actually engage. And I think the social dynamics of this whole area are changing rapidly right now. There are an awful lot of small, extremely media-savvy NGOs getting involved. These people know how to get the attention of the press, and they can raise a lot of concerns very, very quickly. I think the——

Mr. EHLERS. The gentleman's time has expired. Next, we will turn to the gentlewoman from Texas, Ms. Johnson.

Ms. JOHNSON. Thank you very much, Mr. Chairman. I guess what I really would like to know up front is, in doing the research, how protected is the environment around the research, and the researchers, are they protected?

Dr. DENISON. I think you have put your finger, Congresswoman, on a real issue, that much of the development of this technology is happening in universities, in small research facilities, that may have a handful of staff, have never heard of EPA or OSHA or other agencies, and are very ill-equipped to understand even the material that they are working with. So, as others have said, outreach to that community and getting practical advice that can be delivered directly to people that are busy and don't have this as their primary concern is a critical part of addressing the supply chain, if you will, the beginning of that supply chain, that is leading to these issues. So, I think that aspect of the occupational exposure, all the way upstream in the development phase, is a critical gap in the current structure.

Dr. TEAGUE. Yes. May I comment on that?

Ms. JOHNSON. Sure.

Dr. TEAGUE. From the Federal Government's perspective, we have been reaching out, as I indicated in my opening comments, very proactively trying to reach all the people who are working with nanoscale materials. The grants themselves specify that all consideration must be given to environment, health, and safety of the researchers. It is stated in all the grants that are awarded by the National Science Foundation, and almost by all the agencies that award grants or contracts to researchers, have specifications in there for protecting the researchers.

I mentioned earlier the document that has been developed to try to communicate to researchers the necessity for their use, and to exercise appropriate precautions in working with nanoscale materials by the National Institute for Occupational Safety and Health. That is being widely disseminated. In fact, coming up next month will be a major meeting of the directors of almost all the national centers on nanotechnology, both within the Department of Energy, the National Science Foundation, and the Department of Defense, in which this information will be focused upon and people will be informed about the recommended practices, from one, to protect people in the workplace, and in the laboratory, as you were just indicating.

Ms. JOHNSON. A university in my area, the University of Texas at Dallas, is very, very interested in nanotechnology research, and

I don't know if they have hit your radar screen or not, but I wonder if they have the information disseminated to them.

Dr. TEAGUE. Whether this particular university has it or not, I would have to ascertain. We can make sure that they do. It has been announced on the NNI website. We have made it available there. It is actually highlighted on the opening webpage of the NNI website, and we have thousands of visitors, new visitors, per day to that website. So I hope they have it. If not, we will ensure that they do.

If I may go back to some comment about how many clicks it takes to get to the NIOSH information. It is actually two clicks to get to that information, just to make sure that it is not deeply imbedded in the NIOSH website. It is very readily accessible.

Ms. JOHNSON. Any other comment? Thank you very much. My time——

Dr. DORAISWAMY. May I——

Ms. JOHNSON. Yes, go ahead.

Dr. DORAISWAMY. Yeah. Since I am representing a company that actually does work with these kinds of materials, I wanted to share our perspective. For all materials that our research professionals and manufacturing workers work with, we have very disciplined and demanding standard operating procedures to minimize exposure risk and avoid releases.

We have, over the years, developed very disciplined process safety management procedures and process hazards analyses. These reviews are very well established in DuPont, and they address facilities, engineering controls, personal protective equipment, work practices, and so on. We are also, as was pointed out earlier, in the process of developing a framework with Environmental Defense that we hope to share widely on how this kind of discipline can be adopted and applied as guidelines for nanoscale materials.

Ms. JOHNSON. Thank you very much.

Mr. EHLERS. The gentlewoman's time has expired. I am next in line, and have a question for Dr. Teague. In relating to Mr. Nordan's testimony, that suggests that a life cycle perspective, that considers manufacturing, use, and disposal is needed to consider the potential risks of nanotechnology.

And Mr. Nordan, I will also suggest that the greatest uncertainty about risk arises from end of product life issues. Your testimony, so far as I have determined, does not mention disposal as an area of concern. I have a great personal concern about that. In fact, that is what got me into politics originally at the county level, when we had terrible solid waste problems, and heap leach flowing into rivers and so forth. I had an environmental interest, so I ran for office in order to clean up the mess. And I have spent more time in landfills, dumps, auto shredders, incinerators, than I suspect anyone else in the room.

What always concerns me is we always tend to find out these things too late. Nickel-cadmium batteries, for example, went into landfills for years before we finally said no, you have to return them to the store and have them disposed of properly. So, I am wondering if you agree with Mr. Nordan's comments about this. I have always argued, by the way, that disposal is the wrong term to use, and when I took office, I tried to get the name changed from

the Kent County Disposal Facility to the Kent County Storage Facility. Just because you put it underground and put dirt over it doesn't mean it is gone. It is not disposed of. It is still there. We are storing it. And so, I have the same concern about nanotechnology products.

What is the situation? To what extent are you looking at disposal areas or end of life issues, and how does that factor into the equation?

Dr. TEAGUE. Well, that it was not being mentioned in my testimony, the written or the oral, is definitely an oversight, because certainly, the waste stream, the fate and transport of nanoscale materials in the environment is of something that is being looked at very carefully by a number of the federal agencies, in particular, the Environmental Protection Agency.

Just recently, in fact, in Fiscal Year '05, and in Fiscal Year '06, there has been a joint activity between the Environmental Protection Agency, the National Science Foundation, the National Institute of Environmental Health Sciences, and the National Institute for Occupational Safety and Health, specifically issuing a joint solicitation to conduct research on the fate in transport of nanoscale materials in the environment resulting from manufacturing or any other movement of those particles into the environment. This year, it is projected for '06 that this solicitation will be on the order of $8 million a year from all four of those agencies, to study this particular aspect of both the manufacture and the eventual disposal of any products that have nanoscale materials in the product.

Mr. EHLERS. Well, a very important aspect is the risk calculations, and——

Dr. TEAGUE. Yes.

Mr. EHLERS. I am a little concerned that this; you say this was an oversight in your testimony. That is frequently the problem. People don't think about these issues until it is too late. Are you looking at the risk factors in each of these areas, of end of product life, as compared to manufacturing and research and so forth? How are you approaching it?

Dr. TEAGUE. Well, certainly, there has been a significant amount of effort put in to looking at the risks associated with not only the manufacture, both in terms of exposure to the worker, but also, there has been some work on what people call the environmental footprint of different manufacturing processes that has been funded, again, by the National Science Foundation and the Environmental Protection Agency.

Just recently, there has been a paper issued by Rice University comparing the manufacturing footprint for the manufacturing of nanoscale materials to a lot of other types of manufacturing. In that, the conclusion from that study is that the footprint, environmentally, for manufacturing nanoscale materials is certainly less than some of the more conventional manufacturing processes, like ore refining. Many of the manufacturing processes were actually compared and considered to have an environmental footprint comparable to that for the manufacture of aspirin and the manufacturing of wine.

So, that kind of thing, and the risks associated with both the manufacture and the eventual fate and transport of it, are being looked at quite carefully.

Mr. EHLERS. Well, let me just suggest—just yesterday, I met with the new Assistant Administrator of the EPA, in charge of the Office of Research and Development, Dr. Gray, who is a specialist in risk assessment. I encourage you to have a conversation with him. I want to make sure you are working together on this, the end of life issue, and doing the risk calculations appropriately.

I see two other hands up. Mr. Rejeski.

Mr. REJESKI. Last year, we worked with people at Yale University, and we did an inventory of the life cycle analyses that have been done, and that are underway, for nanobased products, and we would be glad to share that with the committee. One of the issues that they raised, and I think it is an important one, is whether the life cycle analyses that we use with normal materials will actually work with nanoscale materials, because a lot of the risk assessment which you alluded to essentially relates the mass of the material to the risk.

Mr. EHLERS. Yeah.

Mr. REJESKI. And we know from nanoscale materials that the risk is now associated with surface area, surface charge, surface properties, the morphology of the particle. So, I think that is a very, very important question, it is a huge question, about whether the existing suite we have of doing these kinds of analyses, from cradle to grave, will actually be transferable to these new nanobased products, and we haven't answered that.

Mr. EHLERS. I would appreciate it if you would provide us with that, and without objection, that will be entered in the record for this hearing. Dr. Denison.

Dr. DENISON. Just one other quick comment. I think you have put your finger on what amounts to a potential regulatory gap. For example, the FDA has authority to look at the use of nanomaterials in products like sunscreens, pharmaceuticals. We know that those products ultimately get washed down the drain. They end up in the water supply, and the ability of the FDA to actually look at the potential impacts downstream is quite limited.

One recent scientific finding that really amplifies the concern you are raising is that buckyballs, these carbon soccer ball type materials, in water, actually can aggregate, become quite water soluble, and are very potent killers of bacteria, bactericides. Now, you might think that is a good thing, but we like to say, you want to kill bacteria, perhaps, in a hospital bed, but not in a riverbed. So, if these materials are actually getting into the environment, and they are killing bacteria that are at the base of the food web in ecosystems, that could be a really significant impact. So, the life cycle perspective you are talking about is critical.

Mr. EHLERS. Thank you, and I suggest, Dr. Teague, that you also talk to the FDA about these risk assessment issues. My time has expired.

We are very Pavlovian in the Congress. When the bells ring, we go vote. Dr. Schwartz is next in line—pardon? Pardon? Oh. I am sorry. I am sorry. Yes. Mr. Carnahan, the gentleman from Missouri, I am sorry. You have five minutes.

Mr. CARNAHAN. Thank you, Mr. Chairman. I will make mine quick.

First, for the panel. You have discussed potential risk and preliminary studies with the impact of these nanomaterials. Are there any documented human health impacts out there that you know of? Are we still looking at potential risk?

Mr. NORDAN. Well, there are analogues. If your question is, are there studies that exist looking at, for example, the impact of exposure to fullerenes on human beings over X years of time, definitely not. Those materials haven't been made in enough quantity, or released in free form in any way that you would see any empirical results. Probably the best analogue would be a very large body of research on what are usually referred to as ultra-fine particles, that are particles with nanosized dimensions that are formed accidentally, either through things like welding, or diesel fuel exhaust, or volcanic eruptions, that have been shown to have deleterious impacts on human health. In fact, that existing base of research on particles that weren't purposefully engineered is what initially sparked much of the concern over engineered nanoparticles.

Mr. CARNAHAN. Anyone else on the panel?

Dr. TEAGUE. Just to emphasize what Mr. Nordan was saying, I think it is very important that the committee be aware, I suspect you are aware, but there is a significant difference between these incidental nanoparticles, which have been with us for many years, and what we are calling the engineered nanomaterials.

One of the real powers of nanotechnology is that we have the capability to engineer in a controllable way the property of matter at this nanoscale. That has really important implications, in terms of what was mentioned relative to, say, the buckyballs. Because we have this capability to control things and engineer things at the nanoscale, we can study them. We know how to, now, treat the buckyballs so that they will not be detrimental to human health or the environment. We know how to functionalize the surface of these small particles in such a way to make them more benign to both public health and to the environment.

So, we happily are at an early stage, where we not only can study these before the widespread application of the technology and production of large volumes of products, we can understand their behavior, and we have sufficient control to where we can engineer them to be what we would like the properties to be, and hopefully, avoid the negative properties, in terms of adverse impact upon the environment, or upon public health.

Mr. CARNAHAN. And lastly, very quick. I would like to have you grade our current crop of scientists and researchers first, and then, how you think we are doing with training our next generation to deal with this new science of nanotechnology.

Dr. TEAGUE. My own assessment is that we have, in the United States, some of the most outstanding researchers in the world in the field of nanotechnology. Further, primarily through the National Science Foundation, we have educational programs trying to bring them abreast of the whole field of nanotechnology, from K through 12, and then on up through the graduate schools. Outstanding programs are in that area.

Just recently, the National Science Foundation formed a center for informal learning about nanotechnology. This is to go through the museums, to reach out directly to all the public to get them more informed about nanotechnology, and hopefully, to attract many young people into this new field. This is probably one of the new fields which offers as much excitement to draw young people into science and engineering as we have had for a long time. So, I think it is—we have a lot of extremely good scientists in the country, I think some of the leading ones in the world, and I think we are putting in place efforts across the entire age spectrum to draw new people into the field.

Mr. CARNAHAN. I am going to wrap it up, and thank you, Mr. Chairman.

Mr. EHLERS. Thank you very much for cutting it short. We have a series of three votes. It will take us at least 45 minutes to get back, so we would like to wrap this up. Dr. Schwarz, a quick question, and——

Mr. SCHWARZ. Mr. Chairman, thank you very much, a quick statement. I represent at least part of the University of Michigan, which has taken the lead in a lot of nanotechnological advances, and I am also a physician. And this is more of a statement than a question, but I want, when you formulate guidelines for people engaged in all the different forms of nanotechnology, to do this with a great deal of thought, with a great deal of objectivity, and may I please suggest that we do not do anything, as we formulate these regulations, these guidelines, that would allow the Luddites to come out of the wall in this country, like they have in other areas of research, which I don't have to name, and have put us in sixth or seventh or eighth or ninth or God knows what place, in that type of research. We need to be number one in nanotechnology. And the first thing, and a couple of you have tried to do this this morning, and I applaud you for it, is define precisely what nanotechnology is. It is not something really exact that you can pack in a box. You talked about different materials. You talked about the filters, which I thought was very, very good. So, it is a very wide field, and my admonition, friendly admonition, is please, when we do this, let us do it with a good deal of science-based thought, and not be hysterical or print anything or do anything that would lead other people to be hysterical, like actually some NGOs, I might say, whose bread and butter is to instill certain hysterical thoughts in the public.

So, let us stick with sound science, please, sound science, facts. Let people know what nanotechnology is, what it can do, what it can do from a medical standpoint, scientific standpoint, consumer products standpoint, and do it with sound science, and not do it to stir up people out in the hustings, who don't have time to learn precisely what it is.

So, that was the statement, Mr. Chairman, and not a question, but a very friendly admonition, that this is great stuff. The United States needs to be number one, and remain number one in this technology, and it can only do that if we encourage our researchers, if we encourage the commercial sector, and we do our very best to define precisely what nanotechnology is, and it is not something that is going to hurt us. It is something that is going to help us.

Thank you, Mr. Chairman.

Mr. EHLERS. Thank you for the statement, and I would simply add to it, make sure all the regulations apply to imports as well, so we don't put ourselves at a disadvantage. Next, we will go to Mr. Honda for a brief statement.

Mr. HONDA. Thank you, Mr. Chairman. I will be real quick, and I will ditto what the doctor said, except I heard you also say that we have a role, and we are not functioning properly, and we are not looking at it in a very systematic way, so I appreciate your input today.

If you wouldn't mind responding back in writing later on, on issues around end of life issues of nanomaterials, lifecycle, and the term bioaccumulation, those are the kinds of things, I think that we need to understand, so that we are able to be partners in educating the public, and engaging them, if you will, in that, have a blue ribbon taskforce on nanotech in Silicon Valley, and I think that this is going to be a very timely kind of a way to approach the rolling out of our information, and I guess with industry. With Dr. Doraiswamy, I read your material, and I think I heard you say we are doing our part, the government has to do their part. I would like to hear from you, how much of your budget are you putting into not only environmental safety, but part of this whole issue of end of life, bioaccumulation, how much are you looking at that, and how would you recommend that the government partner with industry, and sort of roll this out in a much better way?

Mr. EHLERS. Mr. Honda, could I suggest——

Mr. HONDA. So, I thank you very much.

Mr. EHLERS. Could I suggest we just ask him to submit that for the record?

Mr. HONDA. Yes.

Mr. EHLERS. All right. And Mr. Costa.

Mr. COSTA. Thank you very much, Mr. Chairman. We have to vote. I will be very brief. I think the committee needs to continue to pursue this effort, as it relates to genetically modified foods, and risk assessment versus risk management, as we try to deal with nationwide standards and protocols that now not only have a basis as it relates to our respective states, but on an international basis as well. I would like to see us pursue that, and direct the experts to allow us to pursue an effort that would focus on that risk assessment, risk management as it relates to nationwide safety standards.

Mr. EHLERS. And I would add quickly to that, we also should educate the public about risk management, so they totally understand it.

I am sorry we have to run. Thank you very, very much for your excellent testimony. It was very useful to us as we consider this matter. Further, we will be looking closely at this issue. This is not the last hearing on this topic. We will continue to watch the issue, but certainly appreciate the insight that you have presented to us, and we will continue working to strengthen our knowledge, as well as elicit information from you, and continue to support research in this effort.

With that, I declare the meeting adjourned.

[Whereupon, at 11:35 a.m., the Committee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by E. Clayton Teague, Director, National Nanotechnology Coordination Office

Preface

The responses below are based in part on information received from the 25 agencies currently participating in the National Nanotechnology Initiative (NNI).

Please bear in mind that so-called "nanomaterials" or "nanoparticles" can refer to particles of nanometer scale that exist in nature (e.g., certain types of dust), particles that are produced as an incidental byproduct of human activity (e.g., particles from welding processes or combustion processes), or particles and materials that are purposely engineered in order to take advantage of the unique properties that matter can exhibit at the nanometer scale. In this response to the Questions for the Record below, the shortened term "engineered nanomaterials" is used for the last category.

While it is expected that scientific knowledge and experience with the other categories of nanometer scale materials has much relevance for engineered nanomaterials, the responses below refer only to these purposefully manufactured or engineered nanoscale materials.

Questions submitted by Chairman Sherwood L. Boehlert

Q1. In your testimony, you described an interagency document you are working on that will identify and prioritize information and research needs in the area of environmental and safety issues associated with nanotechnology. When will it be completed and what level of detail will be included in this document? Will it be a "research strategy" that agencies and the research community can use to plan and coordinate investments and measure progress?

A1. The document in preparation will outline the areas of research that need to be addressed in order to better assess the risks associated with engineered nanomaterials. The document is intended to provide guidance to the agencies that fund research, as well as industry and the research community more broadly, as they plan, prioritize, and coordinate investments and activities. The document is intended to be sufficiently detailed to guide investigators and managers in making project-level decisions, yet broad enough to provide a framework for the next five to ten years. The document will be released upon completion of the interagency review process, which is expected to be in Spring 2006.

Q2. In his testimony, Dr. Denison called for the National Academies to help guide the development and implementation of the federal research strategy in the area of environmental and safety issues associated with nanotechnology. Do you agree with his suggestion regarding this role for the National Academies? If not, why not? What do you think are other appropriate roles for the National Academies in this area?

A2. The National Academies is already tasked, per Section 5 of the *21st Century Nanotechnology Research and Development Act* (Public Law 108–153), with a triennial external review of the NNI. We agree that this review should help guide the federal strategy for research on environmental and safety issues associated with nanotechnology. The first such review, commissioned by the National Nanotechnology Coordination Office (NNCO) on behalf of Nanoscale Science, Engineering, and Technology (NSET) Subcommittee, is currently underway; a report is expected imminently.

Dr. Denison's written testimony of November 17 specifically recommended that the National Academies Board on Environmental Studies and Toxicology (BEST) should help guide NNI research strategy with respect to environmental and safety issues. The NNCO has been assured that the current National Academies review is drawing on the expertise of all the appropriate boards within the Academies, and we do not foresee the need for an additional dedicated assessment of environmental and safety issues by BEST. One of the five open meetings of the National Academies Panel to Review the NNI[1] was largely devoted to discussion of environmental, health, and safety issues. The panelists heard presenters from all of the NNI participating agencies involved in these issues, as well as representatives of the research and stakeholder communities.

[1] (March 24, 2005, *http://www4.nas.edu/webcr.nsf/MeetingDisplay5/NMAB-J-04-03-A?OpenDocument*).

Through the NNCO, the NSET Subcommittee has invested nearly $1.4 million in the current National Academies study, has high expectations of its outcome, and sees no need to modify the Academies role at this time. We expect the forthcoming report to provide a balanced assessment of the entire NNI investment strategy, taking into account all of the complimentary activities among the various NNI Program Component Areas. Consistent with the provisions of P.L. 108–153, it should evaluate the extent to which the NNI program has adequately considered ethical, legal, environmental, and other appropriate societal concerns (subsection a, para. 6); make recommendations on policy, programs, and budget changes with respect to nanotechnology R&D (including the NNI investments in environmental, health, and safety research) (subsection a, para. 9); and more generally assess and make recommendations on the NNI's activities with respect to the responsible development of nanotechnology (subsection c).

Q3. In his testimony, Mr. Nordan recommended that the Federal Government establish a National Nanotechnology Toxicology Initiative. Under his proposal, the initiative would be funded at $100 to $200 million annually, and research funding would be allocated to studies of different nanoparticles in proportion to the funding going to their development. Companies would be required to submit their materials for testing as a condition of receiving Small Business Innovation Research grants. Do you support this proposal? If not, why not? If you need additional information to evaluate the proposal, what additional information do you need?

A3. We cannot support Mr. Nordan's proposal. From the information provided in his testimony, his recommendation does not appear to adequately consider the existing federal programs for assessing the toxicity of materials (such as the National Toxicology Program) nor does it properly take into account other current and planned activities related to research on nanomaterials toxicology. Furthermore, the recommended conditions on Small Business Innovation Research (SBIR) grants would place a burden on the recipient companies which other U.S. nanotechnology innovators do not share.

The ultimate goat of the initiative proposed by Mr. Nordan—develop nanotechnology safety and responsibly—is one of the four important goals of the NNI. Achieving this goal wilt require research to understand and address the potential toxicity of engineered nanomaterials and to understand how such materials interact with biological systems. Research in these areas is supported by several agencies, including the National Institute of Environmental Health Sciences (NIEHS), the National Institute for Occupational Safety and Health (NIOSH), the Environmental Protection Agency (EPA), the Department of Defense (DOD), the National Science Foundation (NSF), and the National Cancer Institute (NCI). Through coordinated efforts by these agencies, the NNI is proceeding appropriately to fund and conduct research on the toxicology of engineered nanomaterials with research funding increasing as our understanding of this subject grows.

Arbitrary funding targets such as the proposed $100 million are problematic for two reasons. First: formulaic allocation of resources in proportion to development funding is a poor substitute for a thorough evaluation of research needs. Second: arbitrary funding targets for research on nanotoxicology—toxicology of engineered nanomaterials—*per se* raise basic definitional questions as to what research should be included appropriately as nanotoxicology. Categorization of specific research is problematic because of the great breadth of research necessary for risk assessment. For example, a particular research project focused on understanding the basic properties of interactions of engineered nanomaterials with biosystems would likely be classified as fundamental research and not as nanotoxicology research. However, such basic research contributes significantly to our understanding of this field and provides important information for toxicological studies. As a second example, research and development for new methods for measurement and characterization is not typically categorized as nanotoxicology research. Yet, almost all recent examinations of research needed in this area have indicated that one of the most critical pieces of information needed for comparing toxicological studies of engineered nanomaterials is careful characterization of the materials used for such studies. As a final example, even a great deal of applied research—such as research into exposure to airborne particulate matter in the form of incidental nanoparticles (sometimes termed ultrafines)—contributes significantly to nanotoxicology understanding, but it too would not be classified as such.

Because of these significant problems associated with arbitrary funding targets, the most effective means of addressing concerns in this area is by evaluating potential risks, working to prioritize research needs, and distributing funding as these needs demand and as the merits of specific research proposals warrant. For exam-

ple, the National Toxicology Program, which is performing detailed toxicology studies of various nanomaterials, allocates funding based on the anticipated magnitude of commercial application and likelihood of unintentional exposure.

Special requirements for toxicological assessment on engineered nanomaterials developed through the SBIR and STTR programs would be equally arbitrary. Both of these programs support the pre-commercial phases of new-product-related R&D at small companies. Mr. Nordan's proposal would place a greater burden on them than currently exists for pre-commercial products in development through other routes, for example at larger companies, universities, or federally-funded R&D centers. Requirements for toxicological assessment should have their basis in a reasoned analysis of the risks based on likelihood of exposure and toxicity, not in the source of development funding, and should not interfere with pre-commercial development activities that pose minimal risk to the public.

Q4. In his testimony, Mr. Rejeski called for the creation of an International Nanorisk Characterization Initiative, modeled roughly on the Human Genome Project. The proposed initiative would prioritize risks on a global level, align teams of researchers to address these priorities, and create an information infrastructure to support global collaboration. Do you support this proposal? If not, why not? If you need additional information to evaluate the proposal, what additional information do you need?

A4. We cannot support Mr. Rejeski's proposal. However, the agencies participating in the NNI recognize the importance and the value of building international cooperation and engagement in the responsible development of nanotechnology. The agencies participating in the NNI also agree with the need to "prioritize risks on a global level, align teams of researchers to address these priorities, and create an information infrastructure to support global collaboration" and have been actively pursuing those objectives. The NNI encourages other nations to develop nanotechnology in a responsible manner by engaging in risk-related research as part of their own nanotechnology initiatives. Agencies participating in the NNI have pursued and are pursuing coordination of risk-related research through joint calls for proposals, workshops, data sharing, bilateral engagement, and other activities within existing international forums, including the Organization for Economic Cooperation and Development (OECD), the International Organization for Standards (ISO), and the Asia-Pacific Economic Cooperation (APEC). In addition to participating in, and in some cases leading, nanotechnology activities in these longstanding international bodies, the NNI launched in June 2004 the International Dialogue for the Responsible Research and Development of Nanotechnology, which brought together 25 nations plus the European Commission with the goal of stimulating dialogue among a diversity of nations on issues of mutual concern. More activities and efforts will certainly be necessary in the years ahead, but a new initiative does not appear to be the best solution at this time. Instead we believe that the most effective use of resources is to work diligently within the mechanisms that have already been established, while identifying any needs that may not be covered within the purview of those mechanisms.

Q5. In his testimony, Mr. Rejeski called for the U.S. Government to set a goal of reaching out and engaging at least 3,000 citizens and public opinion leaders around the country over the next year in a discussion of nanotechnology to help build greater public trust in this area. He suggested that this could be done through 20–25 town meetings, listening sessions, and civic forums. Do you believe that this is an appropriate goal and an appropriate method to accomplish this goal? If not, why not? If you need additional information to evaluate the proposal, what additional information do you need?

A5. Without question, public outreach is an important and appropriate goal of the NNI. As such, the NNI already has initiated a number of outreach activities consistent with the overall intent of Mr. Rejeski's suggestion. The Boston Museum of Science reports that 5,400 people participated in presentations and discussions about nanotechnology at the museum in 2004. An exhibit created by Cornell University and funded by NSF has drawn 1.5 million visitors since it began touring U.S. cities in 2003. This children's exhibit, *It's a NanoWorld,* has been on display at Disney's Epcot Center and other venues, has taught parents and teachers about nanotechnology and started discussions with them on the topic.

This year the NSF created two Centers of Nanotechnology in Society and a nationwide network of science museums. Participants in these projects will be engaging in public outreach and identifying best practices for public dialogue. The NSF-sponsored Center for Learning and Teaching in Nanoscale Science and Engineering, hosted by Northwestern University, has a stated goal of reaching one million stu-

dents in grades 7–16 over ten years. It is the largest of many NSF-sponsored nanotechnology projects in the formal education area. University-based centers and networks funded by NSF, NCI, and all the Department of Energy (DOE) Nanoscale Science and Research Centers have some component of community outreach or public engagement in their activities, and NNI-funded researchers have held panels, seminars, and other events to discuss nanotechnology issues with the public in cities including Madison, Wisconsin; Tacoma, Washington; Columbia, South Carolina; Cleveland, Ohio; and Raleigh, North Carolina; among others.

These are just a few of the existing NNI's rapidly expanding efforts at education and public outreach. This approach by the NNI agencies to use primarily locally-based forms of public engagement, utilizing research centers and scientists as experts, is proving to be both economical and effective.

Q6. Do federal agencies currently support research on identifying ways to mitigate the undesirable effects of nanoparticles? If so, please describe such programs and how they are coordinated with programs identifying the risks associated with nanoparticles.

A6. In considering this question, the distinction between engineered nanomaterials and other nanoscale particles provided in the preface should be recalled. Determining and mitigating the undesirable effects of natural and incidental nanoscale particles is an ongoing and major area of research by federal agencies. The parallels and differences in behavior between engineered nanomaterials and these other nanoscale particles are as yet not fully known. In the absence of broad knowledge at this time regarding toxicity and uptake mechanisms, we must first determine what, if any, undesirable effects are associated with engineered nanomaterials. This is an important element of the NNI's environmental, health, and safety (EHS) research agenda, and is a necessary precursor to mitigating any undesirable effects that are identified. Concurrently, the NNI is funding basic research that will provide the foundation for future work in this area, including studies on the fundamental principles that govern behavior of nanostructured materials, which will in turn help us understand and mitigate any possible negative effects.

In addition to this research, there is significant research already being funded under the NNI aimed at mitigating possible undesirable effects of engineered nanomaterials. For example, NSF, the National Institutes of Health, and other NNI agencies have supported research on novel methods for rendering engineered nanomaterials more benign. Rice University researchers have found that they can make carbon nanotubes less toxic by engineering them to be soluble.[2] Additional work, also at Rice University, has found ways of modifying the surfaces of buckyballs to make them less toxic.[3] University of Michigan researchers have found that the cytotoxicity (cell damaging) properties of dendrimers—which have been found to have great promise for destroying cancer cells—can be controlled by engineering dendrimers in particular ways, such as modifying their surfaces to make them neutral instead of charged.

Not only does engineering them this way make them less harmful, but it also makes them better at what they were designed to do in the first place.[4] Many of the nanotechnology development projects supported across NCI's eight Centers of Cancer Nanotechnology Excellence include biocompatibility and toxicity studies relevant to risk identification and mitigation. For example, studies on cadmium-based quantum dots for biomedical imaging and therapeutic applications include research on effectively coating or encapsulating these particles to make them biocompatible and prevent toxic effects during *in vivo* applications. These are a few examples of what we view as one of the principal advantages of the "control at the nanoscale" that nanotechnology entails: tailoring (controlling) the properties of these materials to optimize their beneficial properties, while engineering out any possible undesirable properties.

The results of such research are coordinated with risks identification and assessment through dissemination among the scientific and technological communities as they become available through publications and presentations at conferences and workshops and by sharing the results among the members of the interagency NSET Subcommittee and its Nanotechnology Environmental and Health Implications Working Group.

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[2] "They were so safe, in fact, that no more of the cells exposed to these tubes died than those that died when exposed to a control solution without nanotubes." *http://www.techreview.com/NanoTech/wtr_15847,318,p1.html*

[3] *http://www.sciencenews.org/articles/20041002/fob1.asp*

[4] *http://www.physorg.com/news3420.html*

Question submitted by Representative Michael M. Honda

Q1. What portion of the EHS budget within NNI is currently addressing "end of life" and bioaccumulation aspects of nanomaterials? Describe the characteristics and goals of the research now underway?

A1. As indicated in the answers to Chairman Boehlert's Question 6 above, a significant thrust of the NNI from its inception has been to find ways to engineer nanomaterials from the start with such a degree of control that desirable properties are engineered *in* and undesirable properties are engineered *out.* The true long-term promise of nanoscale manufacturing technology is that it will yield new products and processes that are "green" from the start, minimizing waste (hence landfill use) and energy consumption during the manufacturing process and throughout the product life cycle. NNI agencies also have funded research on use of engineered nanomaterials to remediate toxic waste sites and contaminated groundwater. In that broad sense, much of the NNI investment in long-term nanomaterials and nanomanufacturing research is aimed at addressing the general issue that this question refers to.

Among the functions of NSET's Nanotechnotogy Environmental and Health Implications Working Group are to facilitate the identification, prioritization, and implementation of research and other activities required for the responsible research, development, utilization, and oversight of nanotechnology, including research on methods of life-cycle analysis (LCA).

Solid waste and LCA issues with respect to engineered nanomaterials fall primarily within the purview of the EPA. However, several other agencies (NSF, NIOSH, and now NIEHS) have joined with EPA in funding a series of joint interagency solicitations for research on environmental, health, and safety (EHS) impacts of nanotechnology. "Environmental and biological fate, transport, and transformation of manufactured nanomaterials" is one of three topics covered by this solicitation, funded at approx. $7 million in FY 2005 and expected to grow to $8 million in FY 2006.[5] The solicitation is broad, and covers many EHS-related topics. So far under this solicitation, EPA has funded three grants totaling $0.5 million on life cycle assessment specifically. Research under these grants includes the development of a screening methodology that can be applied to assess the relative magnitudes of potential impacts of future applications of engineered nanomaterials particularly in the areas of membranes, catalysis, and nanotechnology-enabled sensors; developing methods for examining the economic and environmental implications of specific nanotechnology products, processes, and markets; and developing original life cycle inventory data for the manufacture of polymer nanocomposites. Sponsored research in the area of bioaccumulation of engineered nanomaterials includes: quantifying biological effects of quantum dots and monitoring the process of quantum dot uptake and breakdown that result from bacterial metabolism of these particles. The forthcoming EPA White Paper[6] (draft is available for public comment) on nanotechnology will include recommendations for future EPA activities in several areas related to nanotechnology, including environmental fate.

NIEHS and NIEHS/National Toxicology Program are developing systematic methods to determine biological responses to engineered nanomaterials. Acute and chronic exposures and *in vivo* studies are proposed to address questions of systemic distribution of materials, biotransformation and bioaccumulation. As research implementing these criteria proceeds, it should be possible to focus future studies on those characteristics most directly correlated with toxicological effects that may be discovered, and to mitigate them through control of the materials.

There is considerable work ongoing within other NNI agencies (e.g., DOE, DOD) aimed at determining how (and in what quantities and forms) engineered nanomaterials enter organisms and the environment. This information about fate, transport, and uptake needs to be gathered before questions on accumulation can be appropriately addressed.

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[5] *http://es.epa.gov/ncer/rfa/2004/2004_manufactured_nano.html*
[6] *http://www.epa.gov/osa/nanotech.htm*

ANSWERS TO POST-HEARING QUESTIONS

Responses by Krishna C. Doraiswamy, Research Planning Manager, DuPont Central Research and Development

Questions submitted by Representative Michael M. Honda

Q1. What is the nature and extent of research activities underway that are addressing the "end of life" and bioaccumulation aspects of nanomaterials? Is this area receiving adequate attention within the current EHS research effort in nanotechnology?

A1. We would first like to address the second part of the question regarding the need for a better defined research strategy in this area. We will then summarize how DuPont is approaching such research as well as relevant work being done elsewhere that we are aware of.

As described in my testimony, it is important to understand the "end of life" and bioaccumulation aspects of nanoscale materials before they enter widespread commercial use. As with other questions relating to the safety, health and environmental impact of nanoscale materials, these aspects need a structured, disciplined and broadly consistent conceptual framework, which will help to appropriately focus research into these important questions, and to prioritize and guide the development of the appropriate tools and data. Such a framework must recognize and accommodate the essential differences between different kinds of nanoscale materials and the variety of application scenarios in which they are used. These variables will play a major role in determining whether and when a particular material has a significant probability of entering the environment in its nano-form during or at the end of its life cycle and whether such a release could present a significant risk. The answers to these questions will in turn determine the nature and scope of information that is needed for that particular material and application.

The development of this kind of framework, as well as the development and validation of tests, measurement techniques and standards, are of broad relevance. For example, we need to develop testing methods and standards for assessing environmental fate and bioaccumulation of nanomaterials. Knowledge of this kind should, in our view, be actively supported through public funding, and made widely and freely available.

With respect to current research efforts in the public domain, we are aware of some ongoing activity funded by government agencies, e.g., the work funded by NSF and EPA at Purdue (*http://news.uns.purdue.edu/html4ever/2004/040826.Turco.nanogrants.html*), and by the EPA at several universities (*http://es.epa.gov/ncer/nano/research/nano_fate_and_transport.html*). The International Council on Nanotechnology (of which DuPont is a founding member) has recently posted on its website a more complete list of already published work relevant to EHS (*http://icon.rice.edu/research.cfm*), with the intention of keeping this list updated as new information becomes available. While DuPont supports such endeavors, we believe that this work would have greater utility, if it were carried out in the context of a strategic framework as described previously.

With respect to our own efforts, DuPont is evaluating novel nanoparticles, each of which has potential interest for a range of applications. Our current experiments with such materials typically involve relatively small quantities in a controlled research environment. Our immediate objective is to demonstrate the feasibility of particular inventions or innovation concepts, while we continue to focus on addressing lab safety and workplace safety questions that apply to all such materials. Questions regarding "end of life" and bioaccumulation will take on a higher priority for these materials as practical applications emerge and their probability of commercialization increases. Our internal Product Stewardship process, as described in the attached background statement, will then require an appropriate level of attention to questions relating to environmental fate, before a decision is made to scale up to manufacturing volumes. Where our internal process reveals serious concerns about environmental fate issues, such concerns will be addressed prior to commercialization.

Questions relating to "end of life" and bioaccumulation are of immediate relevance to the large number of companies that are developing and marketing proprietary nanoscale materials as primary materials suppliers. Customers for such materials (including DuPont) will usually look to these suppliers for adequate SHE related data. Many of these suppliers are early stage start-ups, who will face obvious practical challenges in carrying out such investigations on their own. Access to public

domain information will clearly help these entities and encourage applications-focused innovation with the materials that they seek to provide.

Q2. Should there be a greater partnership between business and government in carrying out research in this area? Do you have recommendations on how to institute such cooperative R&D activities?

A2. DuPont believes that progress in all areas relating to the SHE aspects of nanoscale materials will be greatly accelerated through active collaborations between all of the stakeholders, including industry, government, academic institutions and NGOs. We believe that government, industry and other stakeholders should work together to define what kinds of data and measurement methods will have the greatest value for different materials in different application scenarios, and should collaborate to develop and validate methods that could set the foundation for future industry standards.

In particular, we would recommend that a multi-stakeholder task force should be established to develop broadly accepted research priorities and a roadmap.

We believe our strongest need is for joint work on establishing basic understanding of how to assess physical-chemical properties, environmental fate, bioaccumulation, and toxicity of nanomaterials. This would include developing methods for tests and gathering baseline information on common materials presently in wide use.

While the private sector needs to contribute expertise and resources to this effort, there is a clear role for public cost sharing recognizing that the data that is generated will not be proprietary. The nature of the research that is needed at this early stage is pre-commercial; the resulting knowledge will ideally benefit all the players.

Research goals that are clearly defined and targeted could be pursued through the formation of consortia, made up of stakeholders with a particular interest in those goals. For example, the Nanoparticle Occupational Safety and Health (NOSH) consortium is a multi-stakeholder group that sharing the cost of R&D to investigate nanoparticle aerosols in the workplace and may provide a benchmark for the formation of similar consortia to address other questions.

Excellent models for collaboration are also offered by the joint efforts in the AIChE's Center for Chemical Process Safety and their Design Institute for Physical Property Data (DIPPR®), as well as by the American Chemistry Council's program to share chemical toxicity data.

ANSWERS TO POST-HEARING QUESTIONS

Responses by David Rejeski, Director, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

Questions submitted by Representative Michael M. Honda

Q1. What is the nature and extent of research activities underway that are addressing the "end of life" and bioaccumulation aspects of nanomaterials? Is this area receiving adequate attention within the current EHS research effort in nanotechnology?

A1. **Thus far, only a handful LCAs on nanotechnologies have been completed.** A summary of the LCAs identified through work done with Yale University is provided in Table 2 (see attachment). For each LCA, the table lists the study year and location, the nanotech sector and product assessed, the focus of the study, and the specific approach used. Also identified are the life cycle phases addressed during each LCA, the technological benefits of the nanomaterial, the environmental benefits and costs, and life stages with the greatest and least benefits compared to traditional products.

The completed LCAs have focused on the automotive, electronic, chemical, and lighting sectors. Performing a LCA of a product is a laborious and potentially costly endeavor. One would not expect that each LCA would include all life stages and quantify all potential impacts. However, **we have preliminarily identified the following gaps that need to be addressed in future research.**

- Evaluation of a greater variety of products across multiple sectors (Table 4 in the enclosed report highlights these gaps).
- Assessment of impacts associated with transportation and end-of-life.
- Inclusion in the analyses of all material inputs, including those related to energy use.
- Development of nanoscale-relevant metrics to better quantify impacts across the life cycle.
- Consideration of the fate of material outputs and possible exposure routes.
- Consideration and explicit evaluation of health and environmental risks.
- Modeling of nano-specific effects, which appear to be ignored in most of the existing LCAs, i.e., normal hazardous waste versus waste considered "hazardous" because it contains nanomaterials.

A search of our recently released environmental, health, and safety (EHS) inventory indicates that there are not many LCAs currently underway or being funded in the United States. A search for the keywords "life cycle analysis" returned five (5) projects with an annual funding of $418,069. The ongoing projects include:

- "A Life Cycle Analysis Approach for Evaluating Future Nanotechnology Applications," funded by the Environmental Protection Agency (EPA) for a total of $100,000 over two years and the continuation of one of the completed projects presented in Table 2.
- "Carbon Nanotube Synthesis: Assessing Economic and Environmental Tradeoffs in Process Design," funded by the National Science Foundation (NSF) for $129,989 over two years.
- "Identifying and Regulating Environmental Impacts of Nanomaterials," funded by NSF for $130,000 for one year.
- "Implications of Nanomaterials Manufacture and Use: Development of a Methodology for Screening Sustainability," funded by EPA for $99,740 for two years.
- "Sustainable Biodegradable Green Nanocomposites From Bacterial Bioplastic for Automotive Applications," funded by EPA for $369,613 over three years.
- EPA has added one additional LCA project for FY 2006 that is not contained in our inventory: "Evaluating the Impacts of Nanomanufacturing via Thermodynamic and Life Cycle Analysis," for $375,000 over two years.

On the international level, our inventory contains one project being funded by the European Union, entitled "SHAPE–RISK: Sharing Experience on Risk Management (Health, Safety, and Environment) to Design Future Industrial Systems," for approximately $544,624 USD over three years. Please note that although we tried

to identify all ongoing and completed LCAs on nanotechnologies, there may be some that were inadvertently missed through this research effort.

The results provided by the LCA inventory paper and the search of our EHS inventory indicate that more attention is needed, especially since nano-based products are already on the market and many more are sure to follow. Few LCAs have been completed that are publicly available. The existing LCAs do not assess nano-specific impacts, such as those related to the hazard potential of nanoparticles. The performed LCAs also assess too few products and life cycle stages to provide a clear picture of the life cycle impacts of nanomaterials. **Future LCAs should focus on evaluating human health and environmental impacts and risks associated specifically with nano-based inputs and products during pre-manufacture activities, product manufacture, packaging and transport, use, and recycling and disposal.** These efforts will help inform and improve safe development, management, and use of nanotechnology as this field moves forward.

Q2. Should there be a greater partnership between business and government in carrying out research in this area? Do you have recommendations on how to institute such cooperative R&D activities?

A2. As I stated in my testimony before your committee, it is unlikely that the United States, or any individual country, will have adequate funds to address all the major existing and emerging risks associated with nanotechnologies, especially across all the potential products and their life cycles. It is therefore necessary to look towards international cooperation and partnerships with industry to fill important gaps and stay in front of any potential risks. In terms of life cycle impacts, industry cooperation is critical because businesses have information that is necessary in assessing impacts during the manufacturing stage. In addition, firms involved in waste management need to become involved to properly assess end-of-life impacts associated with disposal, incineration, recycling, etc.

To initiate and sustain the needed partnerships, it is important that one government agency be designated as the lead. **We would recommend that EPA be given the lead in LCA work in the Federal Government.** Because EPA regulations and voluntary programs affect most points in the product life cycle, this approach represents the best opportunity to have the science inform our public policies as nanotechnology moves forward.

EPA's share of the EH&S research funding under the NNI needs to be increased significantly because of their key, and increasingly important, role in regulation (we believe they should receive at least $10 million, double their current funding level). **$2–3 million of an expanded EPA nano research fund should be dedicated to LCA analyses.** LCAs are needed now for products in the market such as cosmetics and composite materials used in automobiles, sporting goods, etc.

We hope that this information will be useful for the Committee. We would be glad to meet with you, other Committee Members, and staff to discuss these important issues. The inventory can be found on our website: *www.nanotechproject.org*.

Table 2: Summary of Performed Life Cycle Assessments of Nanotechnologies

Reference	Year of Study, Location	Sector	Nanotech Product	Focus of Study	Approach	Life Cycle Phases Included	Tech Benefits	Environmental Benefits	Environmental & Other Costs	Life Stages with Greatest Benefit[a]	Life Stages with Least Benefit[a]
Lloyd and Lave 2003	Year not indicated United States	Auto-motive	clay-polypro-pylene nano-composite in light-duty vehicle body panels	economic and environ-mental impacts comparing nano-composites to steel and aluminum	Economic Input-Output Life Cycle Assessment (EIO-LCA) model developed by Carnegie Melon	Extraction, Production, Use	weight reduction and improved fuel economy; enhanced platelet mechanical properties	overall reduced environmental impact; large energy savings; reduction in fuels, ores, and water use; reduction in GHGs and conventional pollutants, reduction in haz waste generated for the upper bound performance nanocomposite	higher manufacturing cost; increase in haz waste generated for the lower bound performance nanocomposite	Material Production and Use (fuel economy) compared to steel body panels	Petroleum Production compared to steel body panels
Lloyd et al. 2005	2005 and 2030 projected United States	Auto-motive	nano-scale platinum-group metal (PGM) particles in automotive catalysts	PGM that could be saved from nanotech and life cycle benefits from reducing PGM mining and refining	Economic Input-Output Life Cycle Assessment (EIO-LCA) model developed by Carnegie Melon and GaBi software system developed by the University of Stuttgart with PE Product Engineering GmbH	Production and Criteria Air Pollutant Emissions during Use	reduced platinum-group metal (PGM) loading levels by 95%, improved dispersion of metals in auto catalysts	overall reduced environmental impact, large energy savings; reduction in fuels used, reduction in GHGs and criteria air pollutants (2X less criteria air emissions during vehicle use) ; reduction in haz waste generated and toxic releases and transfers	None indicated in comparison to current technology	Production	Not indicated
Volz and Olson 2004 (submitted)	United States	Automoti ve	carbon nanofiber (CNF) reinforced polymers	evaluation of environme ntal impact of different polymer and CNF reinforced polymer alternative s	Ecobilan TEAM software Assessed impacts of global warming, stratospheric ozone depletion, acidification, eutrophication, and total energy consumption at each life stage used carbon black in place of CNF due to data constraints	Certain Processes during Extraction, Production, Use, End-of-Life	Reduced weight, increased structural strength, improved conductivity	NA (not compared to traditional carbon fibers)	Similar impacts among polymers.	Least impact: Extraction	End-of-Life: Global Warming Potential, Acidification, Eutrophication; Use: Ozone Depletion Potential, and Energy Use

Reference	Year of Study, Location	Sector	Nanotech Product	Focus of Study	Approach	Life Cycle Phases Included	Tech Benefits	Environmental Benefits	Environmental & Other Costs	Life Stages with Greatest Benefit[a]	Life Stages with Least Benefit[a]
Steinfeldt et al. 2004 - citing Harsch & Schuckert 1996	Year not indicated Germany	Paint	nano-varnishes	ecological efficiency	comparative ecological life-cycle assessment (nano-varnish compared to water-based, solvent-based, and powder varnishes)	Extraction, Production of components and varnish, Pre-treatment of surface, Varnishing, Use, End-of-Life	allows for application of a thinner coating layer with same functionality of other coatings	5X more resource efficient (far less varnish needed for same effectiveness); 65% lower VOC emissions; 30% lower GHG emissions; lower acidification potential	Not indicated	Extraction, Production, Use (probably due to transportation advantages of lightweight material) compared to other coatings	Application compared to other coatings
Steinfeldt et al. 2004	Not indicated Germany	Chemical / Plastics	nanotube catalytic converter to produce styrene	process innovation	deduction using a "general outline of the technology"	Focus on Process; Used process energy data to estimate overall life cycle energy use	increased energy efficiency	50% lower energy use during styrol synthesis (325 MJ/kg using a nanotube catalytic converter vs. 636 MJ/kg with classic styrol synthesis); 8-9% lower energy use over the entire life cycle; reduction in heavy metal use and associated emissions	potential risks from the use of nanotubes (need to be assessed)	Production compared to an iron-oxide catalytic converter	Not indicated
Steinfeldt et al. 2004	Not indicated Germany (with use of U.S. study data)	Electronics/Display	OLEDs and CNT-FED flat displays compared to CRT, LCD, and plasma displays	nano-innovations and eco-efficiency	qualitative comparison and LCA estimates for CRT and LCD from Socolof et al. 2001	Pre-Production, Production, Use	increased energy efficiency, higher resolution and brightness, full color, lightweight, low cost	greater material and energy efficiency; lower production input for OLEDs; 2X greater energy efficiency in use phase compared to conventional LCDs; 20% lower energy use over entire life cycle compared to LCDs	significant risks not expected	Use	Pre-Production
Steinfeldt et al. 2004	Not indicated Germany	Lighting	white LEDs and quantum dots compared to conventional and energy saving light bulbs	nano-applications and eco-efficiency	Not indicated	Use	High energy intensity and broad visible array; multiple applications	white LEDs more energy efficient than the classical light bulb; white LEDs only more efficient than energy saving bulbs when they reach light efficiency of over 65 lm/W; energy efficiency expected with quantum dots in the future	white LEDs 3X less efficient than an energy saving light bulb	Use compared to classical light bulb	Use compared to energy saving light bulb

Notes: CF = Color Filter; CNT-FED = Carbon Nanotube Field Emitter Display; LCA = Life Cycle Analysis or Assessment; LCD = Liquid Crystal Display; LCI = Life Cycle Inventory; LED = Light Emitting Diode; OLED = Organic Light Emitter Display; PGM = Platinum-Group Metal; TFT = Thin Film Transistor.

[a] Compared to other technologies.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Richard A. Denison, Senior Scientist, Environmental Health Program, Environmental Defense, Washington, D.C.

Questions submitted by Representative Michael M. Honda

Q1. What is the nature and extent of research activities underway that are addressing the "end of life" and bioaccumulation aspects of nanomaterials? Is this area receiving adequate attention within the current EHS research effort in nanotechnology?

A1. Very little research now underway directly addresses these critical questions related to the longer-term risks of nanomaterials. Searches of the databases of current research projects maintained by the USEPA[1] and the Woodrow Wilson Center's Project on Emerging Nanotechnologies[2] yielded only a handful of studies relevant to these two topics—even taking an expansive view of which studies could be considered directly relevant. (The identified studies, all funded by EPA, are summarized in the Appendix.) Total funding for the work ongoing in these areas is less than $1 million annually, truly a drop in the bucket in terms of what is needed.

Areas of needed research

Issue related to end-of-life impacts and the potential for bioaccumulation have been identified by the USEPA as research priorities in its recent Nanotechnology White Paper[3] As EPA states: "Research on the transport and potential transformation of nanomaterials in soil, subsurface, surface waters, waste water, drinking water, and the atmosphere is essential as nanomaterials are used increasingly in products."

To illustrate the range and depth of research questions needing to be addressed, consider this sampling of "high-priority" research questions identified by EPA in its draft white paper:

Transport

- What is the potential for these materials, if released to soil or landfills, to migrate to groundwater and within aquifers, with potential exposure to general populations via groundwater ingestion?
- How do nanomaterials bioaccumulate? Do their unique characteristics affect their bioavailability? Do nanomaterials bioaccumulate to a greater or lesser extent than macroscale or bulk materials?

Transformation

- What are the physicochemical factors that affect the persistence of intentionally produced nanomaterials in the environment?
- Do particular nanomaterials persist in the environment, or undergo degradation via biotic or abiotic processes? If they degrade, what are the byproducts and their characteristics? Is the nanomaterial likely to be in the environment, and thus be available for bioaccumulation/biomagnification?

Treatment

- What is the potential for these materials to bind to soil, subsurface materials, sediment or sludge in waste water treatment plants?
- Are these materials effectively removed from waste water using conventional waste water treatment methods and, if so, by what mechanism?
- Do these materials have an impact on the treatability of other substances in waste water, or on treatment plant performance?
- Are these materials effectively removed in drinking water treatment and, if so, by what mechanism?
- Do these materials have an impact on the removal of other substances during drinking water treatment, or on drinking water treatment plant performance?

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[1] See *http://es.epa.gov/ncer/nano/research/nano_industrial_ecology.html*; and *http://es.epa.gov/ncer/nano/research/nano_fate_and_transport.html.*

[2] See *http://www.nanotechproject.org/index.php?id=18.*

[3] Science Policy Council, U.S. Environmental Protection Agency, Nanotechnology White Paper, External review draft dated 2 December, 2005, available at *http://www.epa.gov/osa/nanotech.htm.*

- When nanomaterials are placed in groundwater treatment, how do they behave over time? Do they move in groundwater? What is their potential for migrating to drinking water wells?
- How effective are existing treatment methods such as carbon adsorption, filtration, and coagulation and settling for treating nanomaterials?

New Methods and Technologies

- What low-cost, portable, and easy-to-use technologies can detect, characterize, and quantify nanomaterials of interest in environmental media?

Release and Exposure

- What tools/resources currently exist for assessing releases and exposures within EPA (chemical release information/monitoring systems (e.g., TRI), measurement tools, models, etc.)? Are these tools/resources adequate to measure, estimate, and assess releases and exposures to nanomaterials? Is degradation of nanomaterials accounted for?
- What research is needed to develop sensors that can detect nanomaterials?

Why worry about the end-of-life of nanomaterial-containing products?

In my testimony, I argued that taking a life cycle view is critical to understanding the potential risks of nanomaterials. It is also critical to identifying opportunities during the process of developing nanomaterials and associated applications to "design out" potential downstream impacts. Let me discuss two real-world examples of bioaccumulation and end-of-life concerns related to products that in the future may well routinely contain nanomaterials, examples that vividly illustrate the need to adopt a life cycle view.

Sunscreens: In my testimony, I made the point that nanomaterials present in products like cosmetics and sunscreens will be washed off and enter water supplies, with "end-of-life" impacts as yet uninvestigated. Quite recently, researchers in Southern California and Switzerland appear to have found direct evidence of ingredients from sunscreens and related products entering surface waters, though the ingredients in question were not nanomaterials.[4] The Southern California researchers found that male fish living near a sewage outfall are accumulating a chemical, oxybenzone, used in sunscreens to protect the skin from the ultraviolet component of sunlight. The chemical appears to be washed off of bodies in the shower, passes through sewage treatment plants unchanged and settles on the sea floor, where bottom-feeding fish eat it. The Swiss research has identified two other substances used in sunscreen and lip balm—octocrylene and 4-methylbenzylidene camphor—that are also building up in fish. The salient point here is that we don't know—but need to determine—whether nanomaterials present in products like sunscreens can potentially survive sewage treatment to enter surface waters, and if they are also bioaccumulative, have the potential to build up in aquatic organisms.

Electronics "recycling": A prime area of application for nanomaterials is in the fabrication of components used in electronics. In my testimony, I noted that the use of nanomaterials in such applications may be unlikely to lead to exposures during product use, but that subsequent disposal or recycling might well pose increased risks. As described below, this potential is more than just theoretical.

In many developed countries, including the U.S., programs are being put in place to collect discarded electronics products such as computers for recycling, motivated by the desire to keep such used products, which can contain a variety of toxic materials, out of landfills and incinerators, as well as to recover any valuable materials. While these programs are well-intentioned, in practice they have led to what many consider an epidemic of so-called "e-waste"—the export to developing countries of our electronics discards. What happens to these materials?

A recent article in *Chemical & Engineering News* describes the end-of-life reality of much of today's electronics recycling programs.[5] Because such recycling is generally not economical in the U.S.,

> ". . .more and more of the used electronic equipment collected for recycling is being shipped to China, India, Pakistan, and Africa, where most of it is disposed

[4] Geoffrey Lean, "If your suntan oil can change the sex of fish, what can do it to you?" *The Independent Online,* 22 January, 2006, available at *http://news.independent.co.uk/environment/article340237.ece.*

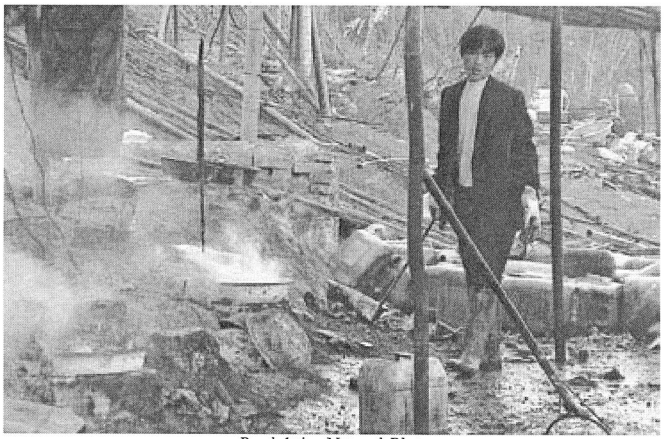
[5] Bette Hileman, "Electronic Waste: States strive to solve burgeoning disposal problem as more waste ends up in developing countries," *Chemical & Engineering News,* January 2, 2006, pp. 18–21, available at *www.cen-online.com.*

of inappropriately. The Government Accountability Office (GAO) estimates that 50–80 percent of the devices collected for recycling in the U.S. end up in Asia or Africa. Although a small percentage of the devices are refurbished and reused abroad, most are disassembled and disposed of in a way that poses risks to workers and the environment."

The photos and captions that follow, taken from the *C&E News* article, tell the end-of-life story:

Electronics Scavenging: About 100,000 migrant workers break down imported computers in hundreds of operations like this one near the Lianjiang River in Guiyu, China.

Basel Action Network Photo



Basel Action Network Photo

Acid Worker: A laborer heats aqua regia-a mixture of nitric acid and hydrochloric acid-to dissolve tiny amounts of gold from computer chips. The worker inhales acid fumes all day as she swirls computer chips in the mixture. The sludge left over from the process is dumped directly into the Lianjiang River in Guiyu, China.

Q2. Should there be a greater partnership between business and government in carrying out research in this area? Do you have recommendations on how to institute such cooperative R&D activities?

A2. As discussed above, there is a tremendous, and currently poorly met, need to identify and address potential health and environmental risks of nanomaterials, including those associated with "end-of-life" impacts and bioaccumulation. As illustrated by the expensive and contentious battles waged over clean-up of toxic "legacy" materials (e.g., lead-based paint, asbestos, hazardous waste sites), failing to consider in advance "end of life" issues and the potential for materials to build up in the environment over time can be very costly for both the government and private industry. Given the anticipated pervasiveness of nanomaterials in a wide range

of applications, it is critical to address these issues at the front end, where solutions can most efficiently and cost-effectively be implemented to prevent widespread and costly environmental and health problems down the road.

Joint funding by government and industry should be one means used to conduct critical health and environmental research in these areas. Initially, government should play the lead role in initiating and coordinating this kind of research. At this early stage, we lack many of the basic tools, methods and instrumentation needed to detect, measure and monitor for nanomaterials in the environment and in living organisms—critical to assessing both end-of-life and bioaccumulation concerns. Because this research cuts across all industries and applications, and given the major investment of the Federal Government in funding nanotechnology development, government needs to play a lead role in developing this "enabling infrastructure," which companies can then use to assess the safety of their own products prior to commercialization.

Government also has an essential role to play in collecting from companies the information needed to best target this research. Private companies are in the best position to identify those materials and applications most likely to be widely commercialized, and they should also be expected to provide the actual materials to be tested. Information on the volume of different materials produced, current and expected uses for those materials, and practices and activities associated with the management of these materials after use (disposal, recovery for recycling, etc.) is key to determining which materials are most important to investigate first. Companies may well be reluctant to share this type of information publicly for fear of exposing competitive information. Government therefore needs to identify mechanisms to obtain the information it needs, while balancing the need to protect legitimate confidential information and to make publicly available as much information as possible to ensure public trust in the process. (Government can, for example, provide information in aggregated forms that do not disclose individual companies' confidential information.) It is essential that a range of stakeholders be informed and involved from the start in the debate over how best to focus such health and environmental research.

Once the needed "infrastructure" is in place, companies should bear the primary responsibility to conduct the needed research on their own nanomaterials and applications, to ensure that they are able to be safely managed throughout their life cycles and will not build up in the environment.

Appendix

First-listed Investigator	Name of Project	Goal	approx. annual funding	funding source
Bhavik R. Bakshi	*Evaluating the Impacts of Nanomanufacturing via Thermodynamic and Life Cycle Analysis*	To develop life cycle inventory data for polymer nanocomposites, test hypotheses for conducting LCAs with limited information, and develop a tool for exploring economic and environmental aspects of alternate manufacturing combinations for selected nanoproducts and conventional processes.	$ 125,000	EPA
Earl Beaver	*Implications of Nanomaterials Manufacture and Use: Development of a Methodology for Screening Sustainability*	The assessment will address the life-cycle costs and benefits including the environmental implications in the production of the nanomaterials.	$ 50,000	EPA
Lee Ferguson	*Chemical and biological behavior of carbon nanotubes in estuarine sedimentary systems*	To investigate the potential for SWCNTs to be transported to, accumulate in, and cause harm to estuarine environments	$ 112,000	EPA
Paul Bertsch	*The bioavailability, toxicity, and trophic transfer of manufactured ZnO particles: a view from the bottom*	To provide data on bioavailability and toxicity of ZnO to bacteria and detritivore and on potential for manufactured nanoparticles to be transferred through the food chain	$ 121,000	EPA
Tohren Kibbey	*Hysteretic accumulation and release of nanomaterials in the vadose zone*	Study vadose zone accumulation and release of manufactured nanomaterials	$ 125,000	EPA
Paul Westerhoff	*The fate, transport, transformation, and toxicity of manufactured nanomaterials in drinking water*	To characterize nanomaterials'properties in aquatic environments; evaluate the removal efficiency of nanomaterials by drinking water treatment processes; and test the toxicity of nanomaterials in drinking water.	$ 117,000	EPA
Mason Tomson	*Adsorption and Release of Contaminants onto Engineered Nanoparticles*	To test the sorption capacity of: carbon nanostructures for PAHs and other common organic contaminants; inorganic nanomaterials for heavy metals; and metal oxide and carbon nanomaterials in the presence of naturally occurring humic materials and surfactants; and to assess the transport of nanoparticles in soils, sediments, and porous media.	$ 111,000	EPA
Jae-Hong Kim	*Fate and Transformation of C_{60} Nanoparticles in Water Treatment Processes*	To examine the response of water-stable fullerene aggregates, to processes that are used in potable water treatment	$ 125,000	EPA
SOURCE: from http://es.epa.gov/ncer/nano/research/index.html			$ 886,000	TOTAL

Appendix 2:

Additional Material for the Record

Woodrow Wilson
International
Center
for Scholars

December 13, 2005

The Honorable Sherwood Boehlert
U.S. House of Representatives
Chairman, Committee on Science
Suite 2320 Rayburn House Office Building
Washington, DC 20515-6301

Dear Congressman Boehlert:

At the November 17th hearing of the Science Committee on "Environmental and Safety Impacts of Nanotechnology: What Research is Needed?" I indicated during my testimony that we would be releasing an inventory and analysis of government spending on environmental, health, and safety research related to nanotechnology. We would like to submit our analysis of the inventory into the hearing record along with this letter outlining some of our primary findings and concerns.

Based on the data in the inventory and our knowledge of nanotech-related EH&S research in the federal agencies, we would like to share the following observations with the Committee:

1. The U.S. is leading the world in the breadth and depth of research addressing the EH&S implications of nanotechnology. Areas key to risk assessment and risk management are all being addressed to some extent within the current nanotechnology research portfolio. However, this does not imply that current research is adequate or appropriately focused if the aim is to ensure the emergence of 'safe' nanotechnologies.

2. There is a gap between the figures reported by the National Nanotechnology Initiative (NNI) and our analysis. The NNI has indicated an anticipated FY06 expenditure of $39 million for research with high relevance to EH&S issues. While this figure is not dissimilar to our estimate of all research with some relevance to the ES&H impact of nanotechnology, we found a much smaller amount of annual funding for research that is highly focused on the potential impact of engineered nanomaterials (around $6 million). Our number does not yet include FY06 projected investments. We expect to add more internal project-specific funding from agencies and initiatives such as NIOSH, Food & Drug Administration, the National Toxicology Program and the NIH Nanoparticle Characterization Laboratory to our database. But we do not anticipate the adjusted figure for highly relevant research to be greater than $15 million.

3. There are gaps in the research portfolio that need to be addressed. These include, but are not limited to:

   - **Little funding is allocated to explore possible links between exposure to nanomaterials and diseases of the lung, heart or skin.** For instance, we are not able to identify U.S. government-sponsored epidemiological research looking at the relationship between exposure and possible long-term health outcomes during the manufacture of nanomaterials. We believe that studying exposure to engineered nanomaterials and evaluating any resulting health effects is essential to assessing and managing potential risk.

   - **Not enough work on life cycle assessment.** Both Congressman Ehlers and Congressman Honda raised important questions concerning our understanding of the life-cycle impacts and risks of nano-based materials and products – from production through use and eventual disposal. Our analysis of government funding shows very little research in this important area.

   - **Virtually no specific funding for safety[1] studies.** We believe that it is important to ensure adequate research in the area of safety, for instance, explosion hazards, spill hazards, etc.

   - **Short term focus in general.** We find little evidence that the government is looking longer term to evaluate the possible risks associated with the next generation of nanotechnologies—active nanostructures that likely will involve developments such as targeted drug delivery systems and advanced nanoelectronics. Though exact risk assessments of such emerging technologies are difficult, some initial upfront thinking is possible based on scenario planning and needs to be encouraged.

4. The gaps in the inventory indicate a lack of an overall, government-wide research strategy for addressing EH&S issues. The currently funded projects appear to follow past trends and reflect the expertise and traditional interests of the EH&S research community. Closing these gaps will require an overarching research strategy that relies on a greater use of directed, intramural funding within relevant agencies, and further investment in research dollars, facilities and trained personnel.

5. Finally, there is little indication of partnerships, either between the U.S. government and other nations, or between government and industry (although EPA, NSF, NIOSH, and NIEHS are negotiating with the European Commission to release a joint research solicitation in FY2007). As I stated in

[1] Referring specifically to the risk of physical injury.

my testimony before your Committee, it is unlikely that the United States, or any individual country, will have adequate funds to address all the major existing and emerging risks associated with nanotechnologies. It is therefore necessary to look towards international cooperation and partnerships with industry to fill important gaps and stay in front of the risks.

The inventory on research related to the ES&H implications of nanotechnology provides a unique tool to help develop appropriate and responsive research strategies, portfolios and partnerships. Continuing input and cooperation from government, as well as industry and other groups, will be essential to its effectiveness. Discussions at the recent December 7-9 OECD meeting on *The Safety of Manufactured Nanomaterials* indicated a willingness on the part of the OECD's Chemical Program to consider taking over and managing the database as a global resource.

We hope that this information will be useful for the Committee. We would be glad to meet with you, other Committee members, and staff to discuss these important issues. The inventory can be found on our website: www.nanotechproject.org.

Respectfully yours,

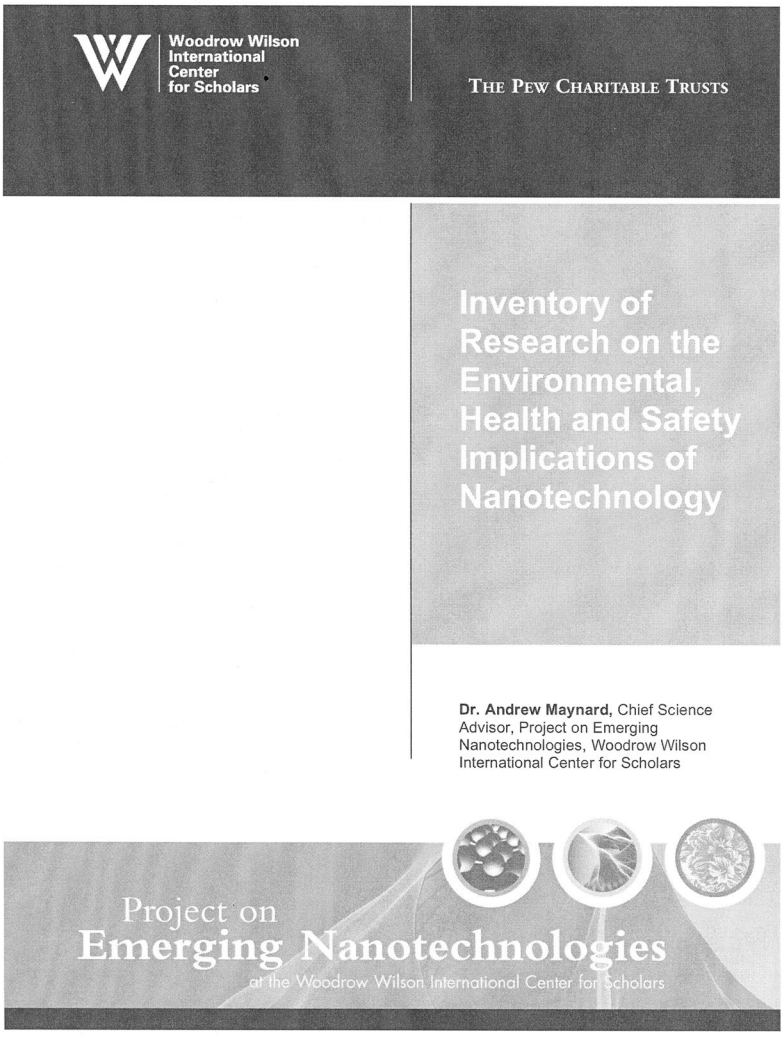
David Rejeski
Director

Dr. Andrew Maynard
Chief Science Advisor

cc.

The Honorable Bart Gordon

Christal Sheppard
Jim Wilson
Marty Spitzer


Woodrow Wilson International Center for Scholars
THE PEW CHARITABLE TRUSTS
Inventory of Research on the Environmental, Health and Safety Implications of Nanotechnology
Dr. Andrew Maynard, Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars
Project on
Emerging Nanotechnologies
at the Woodrow Wilson International Center for Scholars

The **Project on Emerging Nanotechnologies** at the Woodrow Wilson International Center for Scholars was created in partnership with The Pew Charitable Trusts.
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Background

There is growing consensus that over the coming decades nanotechnology will transform virtually every aspect of people's lives. Numerous nanotechnology products—some estimate over 700—are already on the market and many applications are in the final stage of product development.

With any new technology comes uncertainty. Some of these new nanoproducts or manufacturing techniques may have harmful, unintended consequences. Others suggest great health, environmental and economic improvements over the medical, energy, and industrial applications in use today.

The effort to understand and manage nanotechnology's benefits and risks will be a long, perhaps never-ending one. And while there is currently little evidence that engineered nanomaterials and nano-enabled products will create undue harm, the funding for research and development of nanoscience and engineering applications far outpaces the research on possible human health, safety, and environmental impacts.

To date, no single inventory of government-funded risk research has existed. To fill this crucial gap, the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars is compiling an accessible inventory of government-supported research addressing the environmental, human health, and safety (EH&S) implications of nanotechnology.

This inventory is an essential resource for policymakers, researchers, corporations, and others responsible for ensuring nanotechnologies' safe, sustainable development. One critical aim is to facilitate and encourage greater public and private-sector risk-research partnerships, and to foster international research collaborations in the vital area of nanotoxicology and environmental effects.

The first generation of this inventory contains basic information on government-funded, risk-related research projects, including summaries, duration, funding sources, budgets, and, if available, results. The research is categorized on multiple levels. The first layer of categorization analyzes each research project by its relevance to the implications of nanotechnology, whether the nanomaterials under investigation are intentionally manufactured, incidental or naturally occurring, and whether the primary focus is on human health, environment, or safety impacts. A second layer of categorization classifies the research according to its focus within a simplified risk analysis framework. Finally, provision is made for a more detailed, third level of classification according to a range of searchable keywords and phrases. Although not comprehensive, the inventory currently provides the most complete overview of current government-funded research into the EH&S implications of nanotechnology to date.

The inventory is meant to be international and expanding. Every effort is being made to include information on research supported by governments throughout the world. Additions to the inventory will be made as new information is received, and researchers and research managers will be able to contribute new or updated information as their work progresses. Users are encouraged to submit new and updated information to nano@wilsoncenter.org.

The Project on Emerging Nanotechnologies is dedicated to helping ensure that, as nanotechnology research advances, possible risks are minimized, public and consumer engagement remains strong, and the potential benefits of these new technologies are realized.

This inventory is a major initiative to help further and encourage productive private and public-sector EH&S research around the world, and to help create a more complete understanding of how to minimize potential risks posed by emerging nanotechnologies.

The inventory can be accessed online at http://www.nanotechproject.org

Initial analysis of EH&S research[1]

As of November 23rd, the nanotechnology EH&S R&D inventory contained information on 208 research projects (figure 1), representing 6 countries and regions, and accounting for over $38 million of research funding annually. 195 projects are funded by governments ($31 million), with the remaining 13 ($7 million) funded by industry or other organizations, or receiving joint funding. There are 169 projects funded in the United States, with the U.S. federal government funding 161 projects for a total of $27 million annually (including an estimated $3 million being spent annually by NIOSH).

The inventory includes information on research on nanostructured materials from a range of sources, and projects with varying relevance to EH&S implications, thus providing a flexible tool for users with diverse interests. Focusing specifically on research into the implications of engineered nanomaterials, there are 85 projects listed, accounting for nearly $14 million in research funds in 2005 (figure 2). U.S.-supported research accounts for over 60% of the projects, while reported research funding is roughly equal between the U.S. ($7 million) and the EU ($6 million).

The majority of these projects are focused on human health effects, with less than half of the listed research specifically addressing environmental impact (figure 3). There are no listed research projects with a specific focus on workplace safety aspects of nanotechnology other than potential health effects.

Focusing on research within the U.S. with high relevance to the EH&S implications of engineered nanomaterials, federal government-funded research accounts for $6 million of the estimated $7 million being spent annually. Research into hazard and exposure (human and environmental) dominate the research portfolio, with research relevant to risk, control, safety and response accounting for approximately 30% of the portfolio (figure 4). While figure 3 shows no listed projects with a specific focus on safety (other than health effects), figure 4 shows that workplace safety-related research is an integral part of a number of projects.

Figure 4 indicates minimal research on controlling exposure to engineered nanomaterials and their release into the environment, as well as very low levels of research into the diseases and environmental impacts that may result from exposure.

Well over 50% of highly relevant hazard research within the U.S. is focused on human health implications of engineered nanomaterials (figure 5), while a little over a third of all hazard research addresses environmental impact. Probing the health-related, hazard research further, nearly three quarters of all research is related to the lungs, with the remaining research projects covering implications to the skin, central nervous system and cardiovascular system (figure 6). There are no projects listed with specific relevance to the impact of engineered nanomaterials to the gastrointestinal tract.

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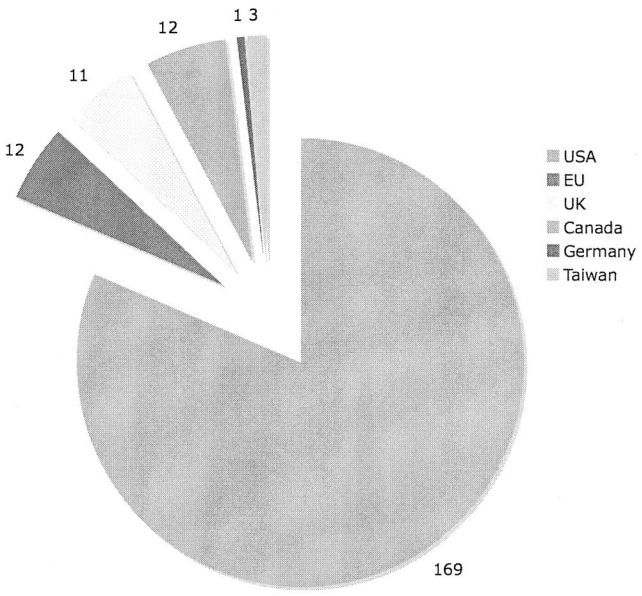
[1] Data analysis is as of November 23, 2005. The current inventory is comprehensive, but not complete. Data known to be under-represented include project-specific funding within NIOSH (which was not released by the agency), and detailed information on nanomaterials-specific projects within the National Toxicology Program. In most cases, data have been presented on project numbers and estimated annual funding; taken together, these present a clearer picture of current research than either one in isolation.

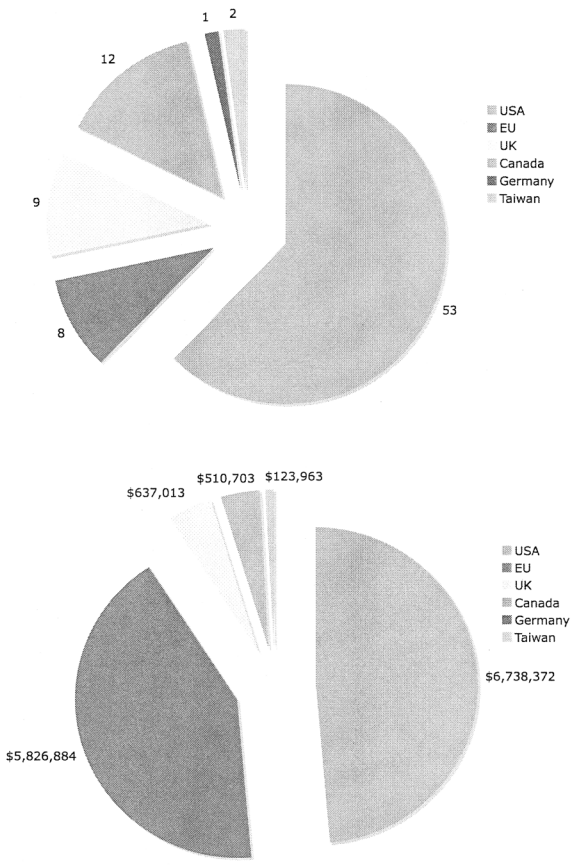
Figure 1:
Total Number of Projects—By Country/Region



Note: Total number of projects: 208. All research projects with some relevance to nanotechnology (including research focused on incidental and natural nanoparticles) have been included.

Figure 2:

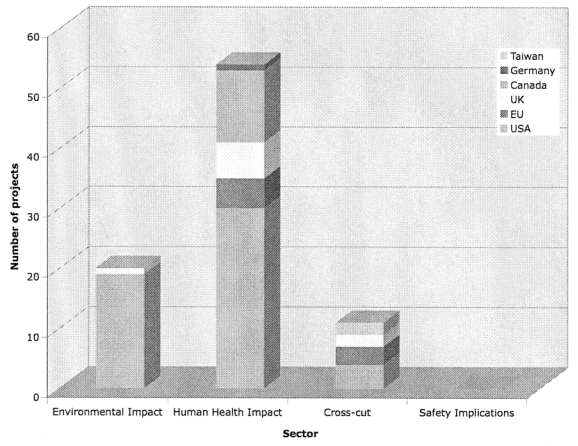
Number and Funding of Highly Relevant Projects on Engineered Nanomaterials—By Country/Region

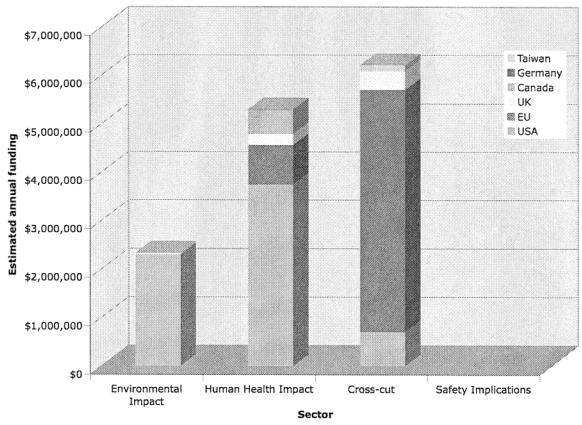


Note: Estimated annual funding for 2005 is shown (total: $14 million). Number of projects: 85. Project-specific funding information was not available from some sources, including intramural research at the National Institute for Occupational Safety and Health.

Figure 3:

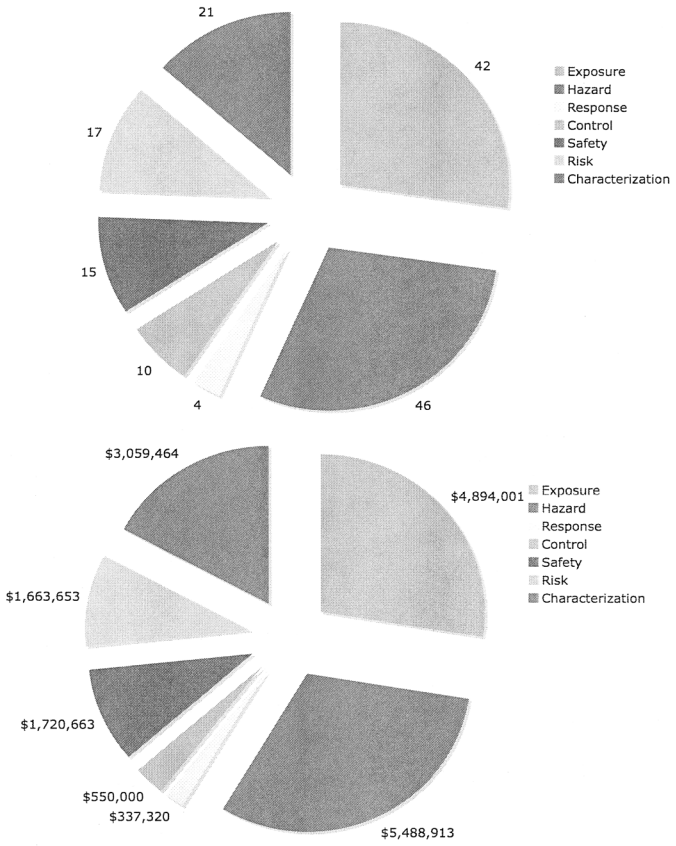
Number and Funding of Highly Relevant Projects on Engineered Nanomaterials—By Impact Sector and Country/Region





Note: Estimated annual funding for 2005 is shown (total: $14 million). Project-specific funding information was not available from some sources, including intramural research at the National Institute for Occupational Safety and Health in the US. Cross-cut funding is dominated by the NANOSAFE 2 project in Europe, which has relevance to both human health and environmental impact.

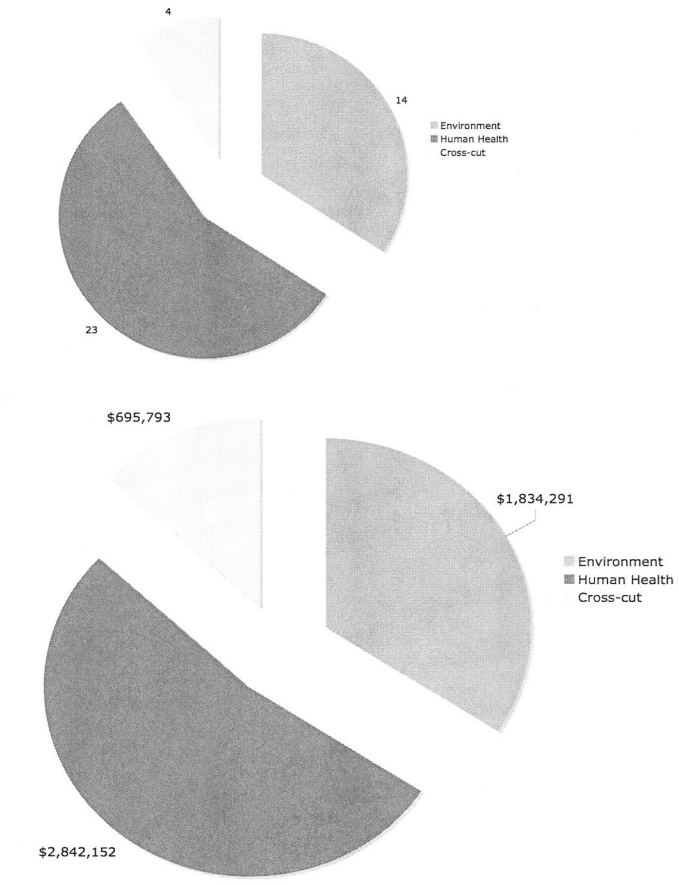
Figure 4:
Number and Funding of Highly Relevant Projects on Engineered Nanomaterials in the United States—By Research Focus



Note: Estimated annual funding for 2005 is shown. Project-specific funding information was not available from some sources, including intramural research at the National Institute for Occupational Safety and Health in the US. Where projects have relevance to multiple research foci, they have been accounted for multiple times.

Figure 5:

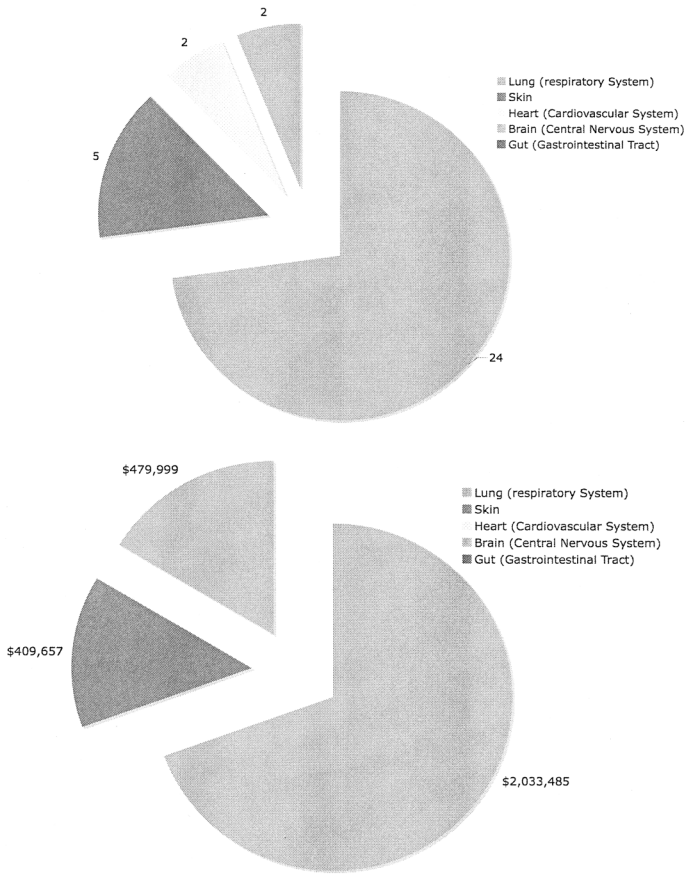
Number and Funding of Highly Relevant Projects on Engineered Nanomaterials Hazard in the United States—By Implication Focus



Note: Estimated annual funding for 2005 is shown (total: $5.3 million). Project-specific funding information was not available from some sources, including intramural research at the National Institute for Occupational Safety and Health in the US.

Figure 6:

Number and Funding of Highly Relevant Projects on Engineered Nanomaterials Hazard in the United States—By Specific Organ



Note: Estimated annual funding for 2005 is shown (total: $3 million). Project-specific funding information was not available from some sources, including intramural research at the National Institute for Occupational Safety and Health and the National Toxicology Program

Supplemental Information

Data quality

Information within the inventory has been collected from publicly available sources and provided by individual investigators. Research has been categorized by principle investigators and research managers, along with staff at the Project on Emerging Nanotechnologies. Every effort has been made to ensure that the information is accurate, although accuracy cannot be guaranteed. Although we aim to ensure that this inventory is as comprehensive as possible, there will be gaps in the data. As new information is made available, the inventory will be updated on a regular basis. Users are encouraged to submit new or updated information to nano@wilsoncenter.org.

Scope of inventory

This inventory is designed to catalogue information on research that has some degree of relevance to the EH&S implications of nanotechnology. It is not the intention to include research which has no clear relevance to EH&S implications. Interpretation of relevant research predominantly lies with those providing information, although new entries submitted to the Project on Emerging Nanotechnologies are, and will be, evaluated prior to posting. However, the National Nanotechnology Initiative definition of implications-relevant research is suggested as a guide:

Research and development (R&D) on the environmental, health, and safety (EHS) implications of nanotechnology includes efforts whose primary purpose is to understand and address potential risks to health and to the environment posed by this technology. Potential risks encompass those resulting from human, animal, or environmental exposure to nanoproducts-here defined as engineered nanoscale materials, nanostructured materials, or nanotechnology-based devices, and their byproducts. (www.nano.gov)

In addition, we encourage the addition of applications-based research that has some clear relevance to understanding the implications of nanotechnology. For example, research into the development of quantum-dot based particles for medical imaging that also addresses the potential toxicity of these particles would be included, as would research into therapeutics-based mechanisms that shed light on biological interactions that could potentially lead to harm. However, applications-based research with no clear focus on EH&S implications would not be considered relevant.

Estimated annual funding

Annual funding is estimated within the inventory where information on funding is available. This estimate is based on total project funding divided by project duration, and it may not be a true representation of expenditure within a given year. Care must be taken in interpreting funding figures, as information is not available for all projects. Some agencies have not released project-specific funding information on their intramural research programs.

Classes of nanomaterials

Engineered nanomaterials: Manufactured materials with engineered structure between approximately 1 nm and 100 nm.

Incidental nanomaterials: Materials with a structure between approximately 1 nm and 100 nm that are produced as a by-product of a process. For instance, welding fume and diesel emission particulates would be considered incidental nanomaterials.

Natural nanomaterials: Materials with a structure between approximately 1 nm and 100 nm that are a result of natural processes. Some particles arising from volcanic emissions, sea spray, and atmospheric gas-to-particle conversion would be considered natural nanomaterials.

Generic: Research that is applicable to the EH&S implications of all nanomaterials, irrespective of class.

Relevance of research

Research is classified has having high, substantial, some or marginal relevance to the EH&S implications of nanotechnology. These are "fuzzy" categories, reflecting the complexity of categorizing research relevance. However, the following can be used as a general guide:

High: Research that is specifically and explicitly focused on the health, environmental and/or safety implications of nanotechnology.

Substantial: Research that is geared towards nanotechnology-based applications or developing fundamental new knowledge on nanoscience but that has substantial and explicit relevance to EH&S implications.

Some: Research that is focused on the application of nanotechnology and developing fundamental new knowledge on nanoscience but that has some relevance to EH&S implications.

Marginal: Fundamental nanoscience and/or nanotechnology applications-based research, which informs understanding on potential EH&S implications in some way.

Broad Research Categories

Research has been categorized into nine broad categories that are related to risk assessment and management. Multiple categories may apply to research projects:

Exposure: Research on exposure to nanomaterials, including human exposure and environmental exposure. This category covers exposure evaluation but not methods development (which comes under *Characterization*).

Hazard: Research associated with the hazardous nature and hazard potential of nanomaterials, including human toxicity and ecotoxicity.

Response: Research into the environmental and human health response to, or impact from, exposure to nanomaterials. This category includes epidemiology and environmental impact studies.

Generation, dispersion, transformation, etc.: Research into the physical, chemical (and some biological) processes that potentially influence the impact of nanomaterials on the environment or human health. This category includes research into material generation and release, transport, accumulation, and physical/chemical transformation.

Safety: Research into aspects of nanotechnology which may potentially lead to physical injury—for instance, fire or explosion hazards.

Control: Research relevant to controlling the release of nanomaterials and controlling exposure to nanomaterials.

Characterization: Research into the characterization of nanomaterials related or relevant to exposure, hazard, response, and control studies.

Risk assessment: Development and application of quantitative and qualitative risk assessments for nanotechnology/nanomaterials.

Risk management: Development and application of risk management models and frameworks for nanotechnology/nanomaterials.

STATEMENT BY KEITH BLAKELY,
CHIEF EXECUTIVE OFFICER
NANODYNAMICS, INC.

As CEO of NanoDynamics and a member of the advisory board of the NanoBusiness Alliance, I would like to thank Chairman Boehlert and the Committee for giving me the opportunity to submit this testimony for the hearing on nanotechnology environment, health and safety issues. I hope that these hearings lead to greater understanding of the true environmental, health, and safety ("EHS") issues of nanotechnology, and that they help to dispel the many myths and misperceptions that are already developing about this new and dynamic field. And most importantly, I hope these hearings lead to an understanding of why it is crucial to support EHS research in nanotechnology at an early stage.

Twenty years ago I founded ART, Inc., widely regarded as one of the leading innovators in advanced materials. The company developed and commercialized dozens of new products, entered into joint development agreements with numerous Fortune 100 organizations, and funded programs at more than 15 universities and national laboratories. In the process, I grew the business to over three hundred employees and tens of millions in revenues. The key to our success was developing good, innovative products that were safe: safe for my employees who manufactured them, safe for my customers who bought them, and safe for the environment long after they were used.

I have brought that same ethos with me to NanoDynamics. NanoDynamics is a fully integrated technology and manufacturing company using nanoscale engineering to improve the lives, health, and safety of our customers. With nanotechnology solutions addressing issues in energy, homeland defense, water, electronics, advanced materials and consumer products, NanoDynamics is committed to delivering the Power of Nanotechnology to the global marketplace. We already have numerous products ready for the marketplace, from nanoscale metals and other materials to our NDMX golf ball and Rev 50 portable solid oxide fuel cell and are working on everything from printable electronics to black mold combating paint.

We have always taken our environmental responsibilities seriously. NanoDynamics hired as one of its first 10 employees an EHS officer and we have been involved in EHS discussions at the NanoBusiness Alliance, the nanotechnology industry association, NIOSH, and several trade organizations. We have also sent staff to participate in EPA meetings discussing nanotechnology regulation. As a father whose children will be using nanotech products, as the CEO of a company that is on the forefront of their production and as a researcher in the field, the development of responsible and fair EHS guidelines for nanotechnology is a matter of great importance in my life.

The National Nanotechnology Initiative defines nanotechnology as the understanding and control of matter at dimensions of roughly one to 100 nanometers (for comparison, a sheet of notebook paper is about 100,000 nanometers thick) and exploiting the unique phenomena that occur at that scale to enable novel applications. Today, nanotech research holds the promise of significant breakthroughs in nearly every industry, through thousands of products and multiple methods of production. Nanosys is working toward high-volume manufacturing of its thin-film solar panels, Nano-Tex is developing wrinkle- and stain-resistant pants that may revitalize the U.S. textile industry, Intel and others are looking at carbon nanotubes as a way to break the next barrier in Moore's law of ever smaller and denser computer memory and companies like Nanosphere and American Pharmaceutical Partners are developing medical applications that promise dramatic improvements in treatment for cancer, Parkinson's disease and Alzheimer's. This breadth of application and the fact that the same nanomaterial may behave very differently based on its size and use is the primary challenge in creating a unified system at the corporate and government level for ensuring EHS safety. For example, aluminum particles at 500nm work well for soda cans while aluminum particles at 5nm make a great explosive.

Another complication is that nanoscale products have been with us for a thousand years, starting with the nano particles of gold that give Venetian stained glass its color to carbon black in inks and pigments to silvers used in the early photographic processes. Even the combustion of gasoline in vehicles produces carbon based nanoparticles. This means that any policy governing nanoparticles and materials may have far-reaching implications that will impact existing and established industries.

Nanotechnology holds the potential for a safer, cleaner and better world. Our goal should be to provide EHS guidelines that will allow us to reap the benefits of that technology in an environmentally responsible fashion.

In looking at the Nanotech space from an EHS perspective it is clear that we must drastically reduce uncertainty surrounding environmental, health, and safety issues of nanomaterials. This is important not only for the safety of the public but also for the success of nanotech industries that depend on consumers not harboring unfounded or ill-informed fears that will keep them from buying nanotech products. Today, not enough fundamental toxicity research has been done on nanoparticles to decisively determine what hazards they may pose to workers, the public, and the environment—or how such hazards, should they exist, might be mitigated. The EHS guidelines we produce to address this must cover all the different aspects of dealing with nanomaterials including:

- Safe Manufacturing;
- Storage and Packaging; and
- Disposal and Recycling

The steps we anticipate must take place to develop these guidelines are as follows:

1. Increase Overall Federal Support for EHS-Focused Research in Nanotech

A massive level of investment is going into nanotech development—$8.6 billion combined in government spending, corporate R&D, and venture capital worldwide in 2004, up 10 percent from 2003. By most measures, the U.S. leads in nanotechnology today, including: absolute public sector spending; patents issued, corporate R&D spending; and scientific publications. In contrast, approximately $40 million or 3.7 percent of the 2006 NNI budget is allocated to researching the health and environmental implications of the technology. This is clearly not sufficient to keep pace with the rate at which the technology is progressing.

While the optimal amount of EHS funding could be the subject of a study unto itself, we believe that *a significant increase to the level of approximately 10 percent of NNI funding is well founded.* This reflects the view that potential future costs associated with litigation, health care, and lost productivity can be avoided with sufficient investment at this juncture.

2. Support EHS Compliance Efforts in Emerging Businesses

The majority of the research being performed with government funding tends to focus on supporting basic research at academic institutions (i.e., labs and universities). Since this basic research is not focused on producing publicly consumable products, there is no impetus to examine all the EHS implications of the technology—particularly those around manufacturing, disposal and recycling. Private corporations like NanoDynamics, on the other hand, have taken a voluntary approach and invested their own capital in being responsible corporate citizens. However, the costs of characterizing new nanomaterials and maintaining compliance can be prohibitive for emerging companies.

We recommend that the government provide incentives for EHS research in the private sector and in particular, focus on helping emerging nanotech businesses perform the work required to examine the EHS implications of their innovations and make them compliant with EHS guidelines. These incentives can take the form of more or better-funded federal centers that provide equipment and services required to investigate the properties of nanomaterials and particles or grants that emerging businesses can acquire to fund research into reducing the toxicity of their products.

3. Coordinate Individual Agencies to Develop EHS Policies for Nanotech

Since nanotechnology spans various industries, we do not recommend that there be a separate or central agency that oversees EHS concerns in this area. Rather, existing agencies concerned with EHS in the industries they regulate develop their own policies and guidelines (for example, the FDA for pharmaceutical and agricultural nanotech applications). This will allow EHS guidelines for a particular nanomaterial or nanoparticle to be appropriately placed in the context of the application in which they are used.

We recommend that a central interagency coordinating program be implemented that coordinates the efforts of the various agencies as they develop their policies and ensures that there is communication between the agencies and consistency in the policies they develop.

4. Promote Public Education around EHS and Nanotech

The public's primary source of education on EHS and Nanotech today is Hollywood movies and science fiction novels. Unsurprisingly, the viewpoint they present is entertaining but fundamentally alarmist and not based in fact. The impact how-

ever is that U.S. consumers are being educated to view nanotech products as harmful without having a clear understanding of their actual behavior. This bias will make it difficult for corporations with nanotech products to succeed in the U.S. marketplace and will eventually force U.S. companies to go abroad to succeed. This is in addition to disadvantaging the American public by denying them the quality of life they could enjoy through the use of nanotech products.

We recommend allocating funding to public education projects that provide a correct and rational evaluation of the risks and benefits of nanotechnology.

In the process of following these recommendations, it is important that we keep in mind the implications EHS policy may have on the U.S. economic climate for nanotech innovation. In this global economy, the U.S. is competing not only to attract innovation and investment from abroad, but also to prevent that same innovation and investment from leaving the country. As we develop our policies we must attempt to not unduly burden innovators, researchers and corporations that are involved in nanotechnology development. Japan, Singapore, Germany and the U.K. have all invested significantly in nanotech development and are actively attempting to attract the innovations and technologies being developed in U.S. institutions and funded by U.S. taxpayers. Losing companies to these foreign territories because of cost of compliance issues would mean we would be foregoing the job creation and economic benefits of our investment in nanotech.

Precedent shows us that a wise investment in research today could save a far greater cost in the future. Asbestos, an extremely effective fire retardant, was installed in millions of homes, businesses, and schools. And while asbestos was an important innovation that allowed us to save lives and make industrial progress, it came at a high cost that could have been avoided by paying attention to and investing in EHS research early in its development. When considering the health care, legal, social and quality of life costs that were incurred as a result of not making this investment, it becomes evident that investing in early EHS studies pays for itself many times over and is in the economic best interests of the public, industry and government. Today, the federal government is the largest single investor in nanotechnology research. As such it must take the lead in identifying the appropriate gaps in EHS knowledge and organize appropriate, objective, and economically sound research studies to assess the risks and rewards of nanomaterials processes and applications. As I mentioned earlier, less than four percent of the National Nanotechnology Initiative budget is devoted to researching health and environmental implications. Given what's at stake, that investment is insufficient. Nanotechnology is new and has the potential to end up, in some form, in the majority of American households. Given this, we should consider spending as much as 10 percent of our research budget, or $100 million annually, during the first several years to learn about the potential impact of these materials. To put the investment in perspective, note that Standard and Poor's has estimated that the cost of liability for asbestos alone could reach $200 billion.

EHS research is equally important to realizing the economic development benefits expected from the government's support of nanotechnology. U.S. companies are in the forefront of this revolution, leveraging our technological prowess to create a new and vibrant manufacturing sector that promises to stimulate job growth at all levels. An investment in EHS will engender the same level of trust from the global market that American pharmaceuticals enjoy and give us access to international export markets and foreign investment. The innovation sparked by this boom will lead to a cleaner environment, higher quality of life and economic development for all.

Today, our technological competencies can be leveraged to both understand the risks of nanotechnology and harness the potential of these exciting materials and processes. It only requires us to make appropriate, informed, and timely investments in the right areas to reap the maximum benefit. I greatly appreciate the opportunity to share my thoughts on this critically important subject.

Approaches to Safe Nanotechnology: An Information Exchange With NIOSH

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH CENTERS FOR DISEASE CONTROL AND PREVENTION

OCTOBER 1, 2005

Director's Message

The field of nanotechnology is advancing rapidly and will likely revolutionize the global industry. As with any new technology, we are faced with many unknowns; all of which raise questions concerning occupational safety and health. The National Institute for Occupational Safety and Health (NIOSH) is committed to ensuring worker protection as nanotechnology develops.

NIOSH has developed the document *Approaches to Safe Nanotechnology: An Information Exchange With NIOSH* to raise awareness of potential safety and health concerns from exposure to nanomaterials. The document also addresses current and future research needs essential to understanding the potential risks that nanotechnology may have to workers.

It is imperative that the scientific community come together to advance our understanding of nanotechnology and its implications in the workplace. I invite you to participate in this process and encourage you to provide feedback, comments, or suggestions regarding the *Approaches to Safe Nanotechnology* document. I also encourage you to share any relevant information or experience pertaining to the field of nanotechnology.

As our knowledge grows, NIOSH plans to provide valuable guidance to the safe handling of nanoparticles and other safe approaches to nanotechnology. This will be an effort that evolves as the technology advances and our knowledge and experience grows.

Thank you.

John Howard, M.D.
Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention

DRAFT (9–30–05)

Approaches to Safe Nanotechnology: An Information Exchange With NIOSH

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Summary

Safety and health practitioners recognize a lack of consistent guidance for the safe handling of nanomaterials. This information gap is critical because of the unknown risk that nanomaterials pose to workers. Experimental studies in rats have shown that at equivalent mass doses, insoluble ultrafine particles (smaller than 100nm) are more potent than large particles of similar composition in causing pulmonary inflammation and lung tumors. Whether these effects would occur in exposed workers is not known. **If engineered nanoparticles involve the same characteristics that seem to be associated with ultrafine particles, they may raise the same concerns.** The greater hazard may relate to the larger number and total surface area of nanoparticles compared with that of the larger particles at the same mass concentration. **Until these preliminary findings and hypotheses are confirmed, we can have no firm knowledge about the health risks that nanoparticles pose to exposed workers.** However, to increase the likelihood of safe work with nanomaterials, we should consider using control measures that are known to work for larger particles. In terms of control measures, nanoparticles appear to have no major physical features that would make them behave differently from larger particles in a control system. Therefore, it may be useful for those working with nanomaterials to employ the range of control technologies, work practices, and personal protective equipment demonstrated to be effective with other fine and ultrafine particles.

This document reviews what is currently known about nanoparticle toxicity and control, but it is only a starting point. The document serves as a request from NIOSH to occupational safety and health practitioners, researchers, product innovators and manufacturers, employers, workers, interest group members, and the general public to exchange information that will ensure that no worker suffers material impairment of safety or health as nanotechnology develops. Opportunities to provide feedback and information are available throughout this document.

Introduction

Nanotechnology is the manipulation of matter on a near-atomic scale to produce new structures, materials, and devices. This technology has the ability to transform many industries and to be applied in many ways to areas ranging from medicine to manufacturing. Research in nanoscale technologies is growing rapidly worldwide. By 2015, the National Science Foundation estimates that nanotechnology will have a $1 trillion impact on the global economy and will employ two million workers, one million of which may be in the United States [Roco and Bainbridge, 2001].

Nanomaterials present new challenges to understanding, predicting, and managing potential health risks to workers. As with any new material being developed, scientific data on the health effects in exposed workers are largely unavailable. **In the case of nanomaterials, the uncertainties are great because the characteristics of nanomaterials may be different from those of the larger particles with the same chemical composition.** Safety and hearth practitioners recognize the critical lack of guidance on the safe handling of nanorilaterials—especially now, when the degree of risk to exposed workers is unknown.

The National Institute for Occupational Safety and Health (NIOSH) is working in parallel with the development and implementation of commercial nanotechnology through (1) conducting strategic planning and research, (2) partnering with public- and private-sector colleagues from the United States and abroad, and (3) making information widely available. The NIOSH goal is to provide national and world leadership for incorporating research findings about the applications and implications of nanotechnology into good occupational safety and health practice for the benefit of all nanotechnology workers.

Intent and Purpose

With the launch of the *Approaches to Safe Nanotechnology* Web page, NIOSH hopes to do the following:

- **Raise awareness** of the occupational safety and health issues being identified in the rapidly moving and changing science and applications and implications of nanotechnology.
- Use the best information available to **make interim recommendations** on occupational safety and health practices in the production and use of nanomaterials. These interim recommendations will be updated as appropriate to reflect new information. They will address key components of occupational safety and health, including monitoring, engineering controls, personal protective equipment, occupational exposure limits, and administrative controls. They will draw from the ongoing NIOSH assessment of current best practices, technical knowledge, and professional judgment. Throughout the development of these guidelines, the utility of a hazard-based approach to risk assessment and control will be evaluated and, where appropriate, recommended.
- **Facilitate an exchange of information** between NIOSH and its external partners from ongoing research, including success stories, applications, and case studies.
- **Respond to requests** from industry, labor, academia, and other partners who are seeking science-based, authoritative guidelines.
- **Identify information gaps** where few or no data exist and where research is needed.

The NIOSH Web site will serve as a starting point for developing good work practices and will set a foundation for developing proactive strategies for responsible development of nanotechnologies in the U.S. workplace. This site will be dynamic in soliciting stakeholder input and featuring regular updates.

Scope

This document has been developed to provide a resource for stakeholders who wish to understand more about the safety and health applications and implications of nanotechnology in the workplace. The information and guidelines presented here

are intended to aid in risk assessments for engineered nanomaterials and to set the stage for the development of more comprehensive guidelines for reducing potential workplace exposures in the wide range of tasks and processes that use nanomaterials. The information in this document will be of specific interest to the following:

- Occupational safety and health professionals who must (1) understand how nanotechnology may affect occupational health and (2) devise strategies for working safely with nanomaterials.
- Researchers working with or planning to work with engineered nanomaterials and studying the potential occupational safety and health impacts of nanomaterials.
- Policy and decision-makers in government agencies and industry.
- Risk evaluation professionals.
- People working with or potentially exposed to engineered nanomaterials in the workplace.

In addition to presenting this document, NIOSH is requesting data and information from key stakeholders that is relevant to the development of occupational safety and health guidelines. The purpose will be to develop a complete resource of occupational safety and health information and recommendations for working safely with nanomaterials based on the best available science. Particular attention will be given to questions about the potential health risks associated with exposure to nanoparticles and to the steps that can be taken to protect worker health. The information provided in this document has been abstracted from peer-reviewed literature currently available. **This document and resulting guidelines will be systematically updated by NIOSH as new information becomes available from NIOSH research or others in the scientific community.**

Established safe work practices are generally based on an understanding of the hazards associated with the chemical composition of a material. Engineered nanomaterials exhibit unique properties that are related to their physical size and structure as well as chemical composition. Considerable uncertainty still exists as to whether these unique properties involve occupational health risks. However, the large body of scientific literature that exists on exposures and responses to ultrafine and other airborne particles in animals and humans will be useful. Current information about the potential health effects of nanomaterials, exposure assessment, and exposure control is limited. **Until further information is available, interim safe Working practices should be developed based on the best available information.** The information and guidelines in this document are intended to aid in risk assessments for engineered nanomaterials and to set the stage for development of more comprehensive guidelines for reducing potential workplace exposures in the wide range of tasks and processes using nanomaterials.

Descriptions and Definitions

Nanotechnology involves the manipulation of matter at nanometer-length[1] scales to produce new materials, structures, and devices. The U.S. National Nanotechnology Initiative (NNI) (see *nano.gov/html/facts/whatIsNano.html*) defines a technology as nanotechnology only if it involves all of the following:

1. Research and technology development involving structures with at least one dimension in the range of one to 100 nanometers (nm), frequently with atomic/molecular precision.
2. Creating and using structures, devices, and systems that have unique properties and functions because of their nanometer-scale dimensions.
3. The ability to control or manipulate on the atomic scale.

Nanotechnology is an enabling technology that offers the potential for unprecedented advances in many diverse fields. The ability to manipulate matter at the atomic or molecular scale makes it possible to form new materials, structures, and devices that exploit the unique physical and chemical properties associated with nanometer-scale structures. The promise of nanotechnology goes far beyond extending the use of current materials. New materials and devices with intricate and closely engineered structures will allow for (1) new directions in optics, electronics, and optoelectronics; (2) development of new medical imaging and treatment technologies; and (3) production of advanced materials with unique properties and high-efficiency energy storage and generation.

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[1] one nanometer (nm) = one billionth of a meter (10^{-9}).

Although nanotechnology-based products are generally thought to be at the pre-competitive stage, an increasing number of products and materials are becoming commercially available. These include nanoscale powders, solutions, and suspensions of nanoscale materials as well as composite materials and devices having a nanostructure.

Nanoscale titanium dioxide, for instance; is finding uses in cosmetics, sun-block creams, and self-cleaning windows. And nanoscale silica is being used as filler in a range of products, including dental fillings. Recently, a number of new or "improved" consumer products using nanotechnology have entered the market—for example, stain and wrinkle-free fabrics incorporating "nanowhiskers," and longer-lasting tennis balls using butyl-rubber/nanoclay composites. Further details on anticipated products can be found at *www.nano.gov/html/facts/appsprod.html.*

A. Nanoparticles

Nanoparticles are particles with diameters between one and 100nm. Nanoparticles may be suspended in a gas (as a nanoaerosol), suspended in a liquid (as a colloid or nanohydrosol),or embedded in a matrix (as a nanocomposite). Nanoparticles are commonly incorporated in a larger matrix or substrate referred to as a nanomaterial. The precise definition of "particle diameter" depends on particle shape as well as how the diameter is measured. Particle morphologies may vary widely at the nanoscale. For instance, carbon fullerenes represent nanoparticles with identical lengths in all directions, whereas single-walled carbon nanotubes (SWCNTs) typically form convoluted, fiber-like nanoparticles with only two dimensions below 100nm. Many regular but nonspherical particle morphologies can be engineered at the nanoscale, including "flower" and "belt"-like structures. For examples of some nanoscale structures, see *www.nanoscience.gatech.edu/zlwang/research.html.*

B. Ultrafine particles

The term "ultrafine particle" has traditionally been used by the aerosol research and occupational and environmental health communities to describe airborne particles typically smaller than 100nm in diameter. Although no formal distinction exists between ultrafine particles and nanoparticles, **the term "ultrafine" is frequently used in the context of manometer-diameter particles that have not been intentionally produced but are the incidental products of processes involving combustion, welding fume, or diesel exhaust.** Likewise, the term "nanoparticle" is frequently used with respect to particles demonstrating size-dependent physicochemical properties, particularly from a materials science perspective, although no formal definition exists. As a result, the two terms are sometimes used to differentiate between engineered (nanoparticle) and incidental (ultrafine) manometer-scale particles.

It is currently unclear whether the use of source-based definitions of nanoparticles and ultrafine particles is justified from a safety and health perspective. This is particularly the case where data on non-engineered, manometer-diameter particles are of direct relevance to the impact of engineered particles. An attempt has been made in this document to preferentially use the term "nanoparticle" where the material or data pertaining to it has some relevance to understanding a particular issue associated with nanotechnology.

C. Engineered nanoparticles

Engineered nanoparticles are intentionally produced, whereas incidental nanoparticles or ultrafine particles are byproducts of processes such as combustion and vaporization. Engineered nanoparticles are designed with very specific properties (including shape, size, surface properties, and chemistry), and collections of the particles in an aerosol, colloid, or powder will reflect these properties. Incidental nanoparticles are generated in a relatively uncontrolled manner and are usually physically and chemically heterogeneous compared with engineered nanoparticles.

D. Nanoaerosol

A nanoaerosol is a collection of nanoparticles suspended in a gas. The particles may be present as discrete nanoparticles, or as agglomerates of nanoparticles. These agglomerates may have diameters larger than 100nm. In the case of an aerosol consisting of micrometer-diameter particles formed as agglomerates of nanoparticles, the definition of nanoaerosol is open to interpretation. It is generally accepted that if the nanostructure associated with the nanoparticles is accessible (through the component nanoparticles being available for either physical, chemical, or biological interactions), then the aerosol may be considered a nanoaerosol. However, if the nanostructure within individual micrometer-diameter particles does not

directly influence particle behavior (for instance, if the nanoparticles were inaccessibly embedded in a solid matrix), the aerosol would not be described as a nanoaerosol.

Potential Health Concerns

Nanotechnology is an emerging field: As such, there are many uncertainties as to whether the unique properties of engineered nanomaterials (which underpin their commercial potential) also pose occupational health risks. These uncertainties arise because of gaps in knowledge about the factors that are essential for predicting health risks—factors such as routes of exposure, movement of materials once they enter the body, and interaction of the materials with the body's biological systems. The potential health risk following exposure to a substance is generally associated with the magnitude and duration of the exposure, the persistence of the material in the body, the inherent toxicity of the material, and the susceptibility or health status of the person. More data are needed on the health risks associated with exposure to engineered nanomaterials. Results of existing studies in animals or humans on exposure and response to ultrafine or other respirable particles may provide a basis for preliminary estimates of the possible adverse health effects from exposures to similar materials on the nanoscale. **It must be recognized that the influence of particle properties, including size and surface area, are not fully understood.** Existing toxicity information about a given material can provide a baseline for anticipating the possible adverse health effects that may occur from exposure to that same material on the nanoscale (see *www.cdc.gov/niosh/homepage.html* for listing).

A. Exposure routes

The most common route of exposure to airborne particles in the workplace is by inhalation. Like deposition of other types of airborne particles, discrete nanoparticle deposition in the respiratory tract is determined by particle diameter. Agglomerates of nanoparticles will deposit according to the diameter of the agglomerate, not constituent nanoparticles. Research is still ongoing to determine the physical factors that contribute to the agglomeration and de-agglomeration of nanoparticles, and the role of these structures in the toxicity of inhaled nanoparticles.

Discrete nanoparticles are deposited in the lungs to a greater extent than larger respirable particles [ICRP, 1994], and deposition may increase during strenuous physical activity [Jaques and Kim, 2000; Daigle et al., 2003] and among persons with existing lung diseases or conditions [Brown et al., 2002]. On the basis of studies reported from animal model studies, discrete nanoparticles may enter the bloodstream and translocate to other organs. [Nemmar et al., 2002; Oberdörster et al., 2002].

Discrete nanoparticles that deposit in the nasal region may be able to enter the brain by translocation along the olfactory nerve, as was recently observed in rats [Oberdörster et al., 2004]. The axonol transport of insoluble particles of 50, 200, and possibly 500nm was also reported in the same research. This exposure route has not been studied in humans, and research is continuing to evaluate its relevance.

Ingestion is another route whereby nanoparticles may enter the body. Ingestion can occur from unintentional hand to mouth transfer of materials; this can occur with traditional materials, and it is scientifically reasonable to assume that it also could happen during handling of materials that contain nanoparticles. Ingestion may also accompany inhalation exposure because particles that are cleared from the respiratory tract via the mucociliary escalator may be swallowed [ICRP, 1994]. Little is known about possible adverse effects from the ingestion of nanoparticles.

Some studies suggest that nanoparticles also could enter the body through the skin during occupational exposure. The U.K. Royal Society and Royal Academy of Engineers have reported that unpublished studies indicate nanoparticles of titanium dioxide used in sunscreens do not penetrate beyond the epidermis [The Royal Society and The Royal Academy of Engineering, 2004]. However, the report also makes a number of recommendations addressing the need for further and more transparent information in the area of nanoparticle dermal penetration. Tinkle et al. [2003] have shown that particles smaller than 1 μm in diameter may penetrate into mechanically flexed skin samples. Research is ongoing to determine whether this is a viable exposure route for nanoparticles *[www.uni-leipzig.de/~*nanoderm/]. Some laboratory studies conducted in vitro using cultured cells have suggested that carbon nanotubes can be absorbed and deposited in skin cells and potentially induce cellular toxicity [Monteiro-Riviere et al., 2005; Shvedova et al., 2003]. It remains Unclear, however, how these findings may be extrapolated to a potential occupational

risk, given that additional data are not yet available for comparing the cell model studies with actual conditions of occupational exposure.

B. Effects seen in animal studies

Experimental studies in rats have shown that at equivalent mass doses, tested insoluble ultrafine particles are more potent than larger particles of similar composition in causing pulmonary inflammation, tissue damage, and lung tumors [Lee et al., 1985; Oberdörster and Yu, 1990; Oberdörster et al., 1994; Heinrich et al., 1995; Driscoll. 1996; Renwick et al., 2004].

Specialized forms of engineered nanoparticles may differ in their toxicity from other nanoparticles. SWCNTs have been evaluated in recent studies of mice and rats exposed via intratracheal instillation. SWCNTs instilled into the lungs of mice and rats produced increased early fibrosis, granulomas, and toxicity in the pulmonary interstitium of the lungs compared with carbon black and quartz [Lam et al., 2004; Warheit et al., 2004]. One study suggested that the SWCNTs may act through a different mechanism than other inhaled contaminants because of the absence of pulmonary inflammation or cellular proliferation [Warheit et al., 2004].

NIOSH researchers recently reported adverse lung effects in mice following exposure to SWCNTs using a dosing technique that correlated with the OSHA Permissible Exposure Limit (PEL) for graphite (5 mg/m^3) [Shvedova et al., 2005]. The study included a dose that was correlated with the dose that would be deposited in a person exposed at the graphite PEL for approximately twenty eight-hour work days. The findings suggest that exposure to SWCNTs in mice leads to pulmonary inflammation, oxidative stress, development of multi-focal granulomatous pneumonia and fibrosis.

C. Observations from epidemiological studies involving fine and ultrafine particles

Epidemiological studies in workers exposed to aerosols including fine and ultrafine particles have reported lung function decrements, adverse respiratory symptoms, chronic obstructive pulmonary disease, and fibrosis [Kreiss et al., 1997; Gardiner et al., 2001; Antonini, 2003]. In addition, some studies have found elevated lung cancer among workers exposed to certain ultrafine particles, e.g., diesel exhaust particulate [Steenland et al., 1998; Garshick et al., 2004] or welding fumes [Antonini, 2003]. The implications of these studies, however, are uncertain because other studies have not found elevated lung cancer, and the precise contribution of the ultrafine particle fraction in workplace aerosols to the observed adverse health effects is still open to question and a matter of active research.

Epidemiological studies in the general population have shown associations between particulate air pollution and increased morbidity and mortality from respiratory and cardiovascular diseases [Dockery et al., 1993; HEI, 2000; Pope et al., 2002; Pope et al., 2004]. Although some epidemiological studies have shown adverse health effects associated with exposure to the ultrafine particulate fraction of air pollution [Peters et al., 1997; Penttinen et al., 2001; Ibald-Mulli et al., 2002], uncertainty exists about the role of ultrafine particles relative to the other air pollutants in causing the observed adverse health effects.

D. Hypotheses from animal and epidemiological studies

Research reported from laboratory animal studies and from human epidemiological studies lead to several hypotheses regarding the potential health effects of engineered nanoparticles. As this research continues, more data will become available to support or refute these hypotheses.

1. Engineered nanoparticles are likely to have health effects similar to well characterized ultrafine particles with similar physical and chemical characteristics.

Studies in rodents and humans support the hypothesis that incidental ultrafine particles nanoparticles may pose a greater respiratory hazard than the same mass of larger particles with similar chemical composition. Studies of existing particles have shown adverse health effects in workers exposed to ultrafine particles (e.g., diesel exhaust particulate, welding fumes); and animal studies have shown that ultrafine particles are more inflammogenic and tumorigenic in the lungs of rats than an equal mass of larger particles of similar composition [Oberdörster and Yu, 1990; Driscoll, 1996; Tran et al., 1999, 2000]. **If engineered nanoparticles involve the same characteristics that seem to be associated with reported effects from ultrafine particles, they may also involve the same concerns.**

Although the characteristics of existing ultrafine particles and engineered nanoparticles may differ substantially, the toxicological and dosimetric principles derived from these studies may be relevant to engineered particles. The biological

mechanisms of particle-related lung diseases (e.g., oxidative stress, inflammation, and production of cytokines, chemokines, and cell growth factors) [Mossman and Churg, 1998; Castranova, 2000] also appear to be involved in the lung responses to ultrafine or nanoparticles [Donaldson et al., 1998; Donaldson and Stone, 2003; Oberdörster et al., 2005]. Toxicological studies have shown that the chemical and physical properties that are important factors influencing the fate and toxicity of ultrafine particles may also be significant for nanoparticles [Duffin et al., 2002; Kreyling et al., 2002; Oberdörstor et al., 2002].

2. Surface area and activity, particle number, and solubility may be better predictors of potential hazard than mass.

The greater potential hazard may relate to the greater number or surface area of nanoparticles compared with that for the same mass concentration of larger particles [Oberdörster et al., 1992; Oberdörster et al., 1994; Peters et al., 1997; Moshammer and Neuberger, 2003]. This hypothesis is based primarily on the pulmonary effects observed in studies of rodents exposed to various types of ultrafine or fine particles (e.g., titanium dioxide, carbon black, barium sulfate, carbon black, diesel soot, coal fly ash, and toner) and in humans exposed to aerosols including nanoparticles (e.g., diesel exhaust and welding fumes). These studies indicate that for a given mass of particles, relatively insoluble nanoparticles are more toxic than larger particles of similar chemical composition and surface properties. Studies of fine and ultrafine particles have shown that particles with less reactive surfaces are less toxic [Tran et al., 1999; Duffin et al., 2002]. However, even particles with low inherent toxicity (e.g., titanium dioxide) have been shown to cause pulmonary inflammation, tissue damage, and fibrosis at sufficiently high particle surface area doses [Oberdörster et al., 1992, 1994; Tran et al., 1999, 2000].

Through engineering, nanomaterials can be generated with specific properties. For example, a recent study has shown the cytotoxicity of water-soluble fullerenes can be reduced by several orders of magnitude by modifying the structure of the fullerene molecules (e.g., by hydroxylation) [Sages et al., 2004]. These structural modifications were shown to reduce the cytotoxicity by reducing the generation of oxygen radicals—which is the probable mechanism by which the cell membrane damage and cell death occurred in laboratory animals.

The studies of ultrafine particles may provide useful data to develop preliminary hazard or risk assessments and to generate hypotheses for further testing. More research is needed of the specific particle properties and other factors that influence the toxicity and disease development associated with airborne particles, including those characteristics that may be most predictive of the potential safety or toxicity of new engineered nanoparticles.

Potential Safety Hazards

Very little is known about the safety risks that engineered nanomaterials might pose, beyond some data indicating that they possess certain properties associated with safety hazards in traditional materials. From currently available information, the potential safety concerns most likely would involve catalytic effects or fire and explosion hazards if nanomaterials are found to behave similarly to traditional materials in key respects.

A. Fire and explosion

Although insufficient information exists to predict the fire and explosion risk associated with nanoscale powders, **nanoscale combustible material could present a higher risk than a similar quantity of coarser material, given its unique properties** [HSE, 2004]. Decreasing the particle size of combustible materials can increase combustion potential and combustion rate, leading to the possibility of relatively inert materials becoming as highly reactive as nanomaterials. Dispersions of combustible nanomaterial in air may present a greater safety risk than dispersions of non-nanomaterials with similar compositions. Some nanomaterials are designed to generate heat through the progression of reactions at the nanoscale. Such materials may present a fire hazard that is unique to engineered nanomaterials. In the case of some metals, explosion risk can increase significantly as particle size decreases.

The greater activity of nanoscale materials forms a basis for research into nanoenergetics. For instance, nanoscale Al/MoO_3 thermites ignite more than 300 times faster than corresponding micrometer-scale material [Granier and Pantoya, 2004].

B. Catalytic reaction

Nanometer-diameter particles and nanostructured porous materials have been used for many years as effective catalysts for increasing the rate of reactions or decreasing the necessary temperature for reactions to occur in liquids and gases. Depending on their composition and structure, some nanomaterials may initiate catalytic reactions that would not otherwise be anticipated from their chemical composition alone [Pritchard, 2004].

Working With Engineered Nanomaterials

Engineered nanomaterials are diverse in their physical, chemical, and biological nature. The processes used in research, material development, production, and use or introduction of nanomaterials have the potential to vary greatly. **Until further information on the possible health risks and extent of occupational exposure to nanomaterials becomes available, interim precautionary measures should be developed and implemented.** These measures should focus on the development of safe working practices tailored to specific processes and materials where workers might be exposed. Hazard information that is available about common materials that are being manufactured in the nanometer range (for example, TiO_2) should be considered as a starting point in developing any work practices. The following guidelines are designed to aid in risk assessments for engineered nanomaterials, and for reducing the risk of exposure in the workplace. Using a risk-based approach to assess a given process and develop precautionary measures is consistent with good professional occupational safety and health practice and with those recommended by the U.K. Royal Society and Royal Academy of Engineers [The Royal Society and The Royal Academy of Engineering, 2004].

A. Potential for occupational exposure

Very few studies have been measured exposure to nanoparticles that are purposely produced and not incidental to an industrial process. In general, it is likely that processes generating nanomaterials in the gas phase, or using or producing nanomaterials as powders or slurries/suspensions/solutions (i.e., in liquid media) pose the greatest risk for releasing nanoparticles. In addition, maintenance on production systems (including cleaning and disposal of materials from dust collection systems) is likely to result in exposure to nanoparticles if it involves disturbing deposited nanomaterial. Exposures associated with waste streams containing nanomaterials may also occur.

The magnitude of exposure to nanoparticles when working with nanopowders depends on the likelihood of particles being released from the powders during handling. Studies on exposure to SWCNTs have indicated that although the raw material may release visible particles a few millimeters in diameter into the air when handled, the release rate of inhalable and respirable particles is relatively low (on a mass or number basis) compared with other nanopowders [Maynard et al., 2004]. Since data are generally lacking with regard to the generation of inhalable/respirable particles during the production and use of engineered nanomaterials, further research is required to determine exposures under various conditions.

Devices comprised of nanostructures, such as integrated circuits, pose a minimal risk of exposure to nanoparticles during handling. However, some of the processes used in their production may lead to exposure to nanoparticles (for example, exposure to commercial polishing compounds that contain nanoscale particles, or exposure to nanoscale particles that are inadvertently dispersed or created during the manufacturing and handling processes). Likewise, large-scale components formed from nanocomposites will most likely not present significant exposure potential. However, if such materials are used or handled in such a manner that can generate nanostructured particles (e.g., cutting, grinding), or undergo degradation processes that lead to the release of nanostructured material, then a potential exposure may occur by the inhalation, ingestion, and/or dermal penetration of these particles.

B. Factors affecting exposure to nanoparticles

Factors affecting exposure to engineered nanoparticles will include the amount of material being used and whether the material can be easily dispersed (in the case of a powder) or form airborne sprays or droplets (in the case of suspensions). The degree of containment and duration of use will also influence exposure. In the case of airborne material, particle or droplet size will determine whether the material can enter the respiratory tract and where it is most likely to deposit. Inhaled particles smaller than 10 μm in diameter have some probability of penetrating to and being deposited in the gas exchange (alveolar) region of the lungs, but there is at least a 50 percent probability that particles smaller than 4 μm in diameter will reach the gas-exchange region [Lippmann, 1977; ICRP, 1994; ISO, 1995]. Particles

that are capable of being deposited in the gas exchange region of the lungs are considered respirable particles. **The mass deposition fraction of discrete nanoparticles (i.e.,** <100nm) is greater in the human respiratory tract than that for larger respirable particles. Up to 50 percent of inhaled nanoparticles may deposit in the gas-exchange region [ICRP, 1994]. For inhaled nanoparticles smaller than approximately 30nm, an increasing mass fraction of particles is predicted to deposit in the upper airways of the human respiratory tract [ICRP, 1994]. At present there is insufficient information to predict situations and scenarios that are likely to lead to exposure to nanomaterials. However, some of those workplace factors that can increase the potential for exposure include the following:

- Working with nanomaterials in liquid media without adequate protection (e.g., gloves) will increase the risk of skin exposure.
- Working with nanomaterials in liquid media during pouring or mixing operations, or where a high degree of agitation is involved, will lead to an increased likelihood of inhalable and respirable droplets being formed.
- Generating nanoparticles in the gas phase in non-enclosed systems will increase the chances of aerosol release to the workplace.
- Handling nanostructured powders will lead to the possibility of aerosolization.
- Maintenance on equipment and processes used to produce or fabricate nanomaterials will pose a potential for exposure to workers performing these tasks.
- Cleaning of dust collection systems used to capture nanoparticles can pose a potential for both skin and inhalation exposure.

Exposure Assessment and Characterization

Until more information is available on the mechanisms underlying nanoparticle toxicity, it is uncertain as to what measurement techniques should be used to monitor exposures in the workplace. If the qualitative assessment of a process has identified potential exposure points and leads to the decision to measure nanoparticles, several factors must be kept in mind. Current research indicates that mass and bulk chemistry may be less important than particle size, surface area, and surface chemistry (or activity) for nanostructured materials [Oberdörster et al., 1992, 1994]. Research is still ongoing into the relative importance of these different exposure metrics, and how to best characterize exposures against them. Once the decision has been made to measure exposure, the metric to be used will depend on availability of sampling equipment or instruments and experience with those methods or instruments. **Regardless of the metric and method selected, it is critical that measurements be conducted before production or processing of a nanoparticle to obtain background data.** Measurements made during production or processing can then be evaluated to determine if there has been an increase in the metric selected. NIOSH intends to release the results of its research on this site and invites additional information and comments to be submitted.

A. Monitoring workplace exposures

Although research continues to address questions of nanoparticle toxicity, a number of exposure assessment approaches can be instituted to determine worker exposures. These assessments can often be performed using traditional industrial hygiene sampling methods that include the use of samplers placed at static locations (area sampling), samples collected in the breathing zone of the worker (personal sampling), or real-time measurements of exposure that can be personal or static. In general, personal sampling is preferred to ensure an accurate representation of the worker's exposure, whereas area samples (e.g., size-fractionated aerosol samples) and real-time (direct-reading) exposure measurements may be more useful for evaluating the need for improvement of engineering controls and work practices.

Many of the sampling techniques that are available for measuring airborne nanoaerosols vary in complexity but can provide useful information for evaluating occupational exposures with respect to particle size, mass, surface area, number concentration, composition, and surface chemistry. Unfortunately, relatively few of these techniques are readily applicable to routine exposure monitoring. These measurement techniques are described below along with their applicability for monitoring nanometer aerosols.

For each measurement technique used, it is vital that the key parameters associated with the technique and sampling methodology be recorded when measuring exposure to nanoaerosols. This should include the response range of the instrumentation, whether personal or static measurements are made, and the location of all po-

tential aerosol sources. Comprehensive documentation will facilitate comparison of exposure measurements and aid the re-interpretation of historic data as further information is developed on appropriate exposure metrics.

Size-fractionated aerosol sampling

Studies have indicated that particle size plays an important role in determining the potential effects of nanoparticles in the respiratory system, either by influencing the physical, chemical, and biological nature of the material, affecting the surface area of deposited particles, or enabling deposited particles to move to other parts of the body. Animal studies indicate that the toxicity of nanometer aerosols is more closely associated with aerosol surface area and particle number than the mass concentrations of the aerosol. However, mass concentration measurements may be applicable for evaluating occupational exposure to nanometer aerosols where a good correlation between the surface area of the aerosol and mass concentration can be determined.

Aerosol samples can be collected using inhalable, thoracic, or respirable samplers, depending on the region of the respiratory system most susceptible to the inhaled particles. **Current information suggests that the gas-exchange region of the lungs is particularly susceptible to nanomaterials [ICRP, 1994], suggesting the use of respirable samplers.** Respirable fraction samplers will also collect a nominal amount of nanometer-diameter particles that can deposit in the upper airways and ultimately cleared or transported to other parts of the body.

Respirable fraction samplers allow mass-based exposure measurements to be made using gravimetric and/or chemical analysis [NIOSH, 1994a]. However, they do not provide information on aerosol number, size, or surface area concentration, unless the relationship between different exposure metrics for the aerosol (e.g., density, particle shape) has been previously characterized. Currently, no commercially available personal samplers are designed to measure the particle number, surface area, or mass concentration of nanometer aerosols. However, several methods are available that can be used to estimate surface area, number, or mass concentration for particles smaller than 100nm.

In the absence of specific exposure limits or guidelines for engineered nanoparticles, exposure data gathered from the use of respirable samplers [NIOSH, 1994b] can be used to determine the need for engineering controls or work practices and for routine exposure monitoring of processes and job tasks. When chemical components of the sample need to be identified, chemical analysis of the filter samples can permit smaller quantities of material to be quantified, with the limits of quantification depending on the technique selected [NIOSH, 1994a]. The use of conventional impactor designs to assess nanoparticle exposure is limited, since practical impaction limits are 200 to 300nm. Low-pressure cascade impactors that can measure particles to ≥50nm may be used for static sampling, since their size and complexity preclude their use as personal samplers [Marple et al., 2001, Hinds, 1999]. A personal cascade impactor is available with a lower aerosol cut point of 250nm [Misra et al., 2002], allowing an approximation of nanometer particle mass concentration in the worker's breathing zone. For each method, the detection limits are of the order of a few micrograms of material on a filter or collection substrate [Vaughan et al., 1989]. Cascade impactor exposure data gathered from worksites where nanomaterials are being processed or handled can be used to make assessments as to the efficacy of exposure control measures.

Real-time aerosol sampling

The real-time (direct-reading) measurement of nanometer aerosol concentrations is limited by the sensitivity of the instrument to detect small particles. Many real-time aerosol mass monitors used in the workplace rely on light scattering from groups of particles (photometers). This methodology is generally insensitive to particles smaller than 300nm [Hinds, 1999]. Optical instruments that size individual particles and convert the measured distribution to a mass concentration are similarly limited to particles larger than 100 to 300nm.

The Scanning Mobility Particle Sizer (S14IPS) is widely used as a research tool for characterizing nanometer aerosols, although its applicability for use in the workplace may be limited because of its size, cost, and the inclusion of a radioactive source. The Electrical Low Pressure Impactor (ELPI) is an alternative instrument that combines a cascade impactor with real-time aerosol charge measurements to measure size distributions [Keskinen et al., 1992].

Surface area measurements

Relatively few techniques exist to monitor exposures with respect to aerosol surface area. Isothermal adsorption is a standard off-line technique used to

measure the specific surface area of powders that could be adapted to measure the specific surface area of collected aerosol samples. For example, the surface area of particulate material (e.g., using either a bulk or an aerosol sample) can be measured in the laboratory using a gas adsorption method (e.g., Brunauer, Emmett, and Teller, BET) [Brunauer et al., 1938]. However, the BET method requires relatively large quantities of material, and measurements are influenced by particle porosity and adsorption gas characteristics.

The first instrument designed to measure aerosol surface-area was the epiphaniometer [Baltensperger et al., 1988]. This device measures the Fuchs or active surface-area of the aerosols by measuring the attachment rate of radioactive ions. For aerosols less than approximately 100nm in size, measurement of the Fuchs surface area is probably a good indicator of external surface-area (or geometric surface area). However, for aerosols greater than approximately 1 μm the relationship with geometric particle surface-area is lost [Fuchs, 1964]. Measurements of active surface-area are generally insensitive to particle porosity. The epiphaniometer is well suited to widespread use in the workplace because of the inclusion of a radioactive source and the lack of effective temporal resolution.

This same measurement principle can be applied with the use of a portable aerosol diffusion charger. Studies have shown that these devices provide a good estimate of aerosol surface area when the airborne particles are smaller than 100nm in diameter. For larger particles, diffusion chargers underestimate aerosol surface area. However, further research is needed to evaluate the degree of underestimation. Extensive field evaluations of commercial instruments are yet to be reported. However, laboratory evaluations with monodisperse silver particles have shown that two commercially available diffusion chargers can provide good measurement data on aerosol surface area for particles smaller than 100nm in diameter but underestimate the aerosol surface area for particles larger than 100nm in diameter [Ku and Maynard (in press)].

Particle number concentration measurement

The importance of a particle number concentration as an exposure metric is not clear from the toxicity data. In many cases, health end points appear to be more closely related with particle surface area rather than particle number. However, the number of particles deposited in the respiratory tract or other organ systems may play an important role.

Aerosol particle number concentration can be measured relatively easily using Condensation Particle Counters (CPCs). These are available as hand-held static instruments, and they are generally sensitive to particles greater than 10 to 20nm in diameter. CPCs designed for the workplace do not have discrete size-selective inputs, and so they are typically sensitive to particles up to micrometers in diameter. Commercial size-selective inlets are not available to restrict CPCs to the nanoparticle size range; however, the technology exists to construct size-selective inlets based on particle mobility, or possibly inertial pre-separation. An alternative approach to estimating nanoparticle concentrations using a CPC is to use the instrument in parallel with an optical particle counter. The difference in particle count between the instruments will provide an indication of particle number concentration between the lower CPC detectable particle diameter and the lower optical particle diameter detectable (typically 300 to 500nm).

A critical issue when characterizing exposure using particle number concentration is selectivity. **Nanoparticles are ubiquitous in many workplaces,** from sources such as combustion, vehicle emissions, and infiltration of outside air. Particle counters are generally insensitive to particle source or composition **making it difficult to differentiate between incidental and process-related nanoparticles using number concentration alone.** In a study of aerosol exposures while bagging carbon black, Kuhlbusch et al. [2004] found that peaks in number concentration measurements were associated with emissions from fork lift trucks and gas burners in the vicinity, rather than the process under investigation. Although this issue is not unique to particle number concentration measurements, orders of magnitude difference can exist in aerosol number concentrations depending on concomitant sources of particle emissions.

Although using nanoparticle number concentration as an exposure measurement may not be consistent with exposure metrics being used in animal toxicity studies, **such measurements may be a useful indicator for identifying nanoparticle emissions and determining the efficacy of control measures.** Portable CPCs are capable of measuring localized aerosol concentrations, allowing the assessment of particle releases occurring at various processes and job tasks [Brouwer et al., 2004].

Surface Area Estimation

Information about the relationship between different measurement metrics can be used for estimating aerosol surface area. If the size distribution of an aerosol remains consistent, the relationship between number, surface area, and mass metrics will be constant. In particular, mass concentration measurements can be used for deriving surface area concentrations, assuming the constant of proportionality is known. This constant is the specific surface area (surface to mass ratio).

Size distribution measurements obtained through sample analysis by transmission electron microscopy may also be used to estimate aerosol surface area. If the measurements are weighted by particle number, information about particle geometry will be needed to estimate the surface area of particles with a given diameter. If the measurements are weighted by mass, additional information about particle density will be required.

If the airborne aerosol has a lognormal size distribution, the surface-area concentration can be derived using three independent measurements. An approach has been proposed using three simultaneous measurements of aerosol that included mass concentration, number concentration, and charge [Woo et al., 2001]. With knowledge of the response function of each instrument, minimization techniques can be used to estimate the parameters of the lognormal distribution leading to the three measurements used in estimating the aerosol surface area.

An alternative approach has been proposed whereby independent measurements of aerosol number and mass concentration are made, and the surface area is estimated by assuming the geometric standard deviation of the (assumed) lognormal distribution [Maynard, 2003]. This method has the advantage of simplicity by relying on portable instruments that are finding increasing application in the workplace. Theoretical calculations have shown that estimates may be up to a factor of ten different from the actual aerosol surface-area, particularly when the aerosol has a bimodal distribution. Field measurements indicate that estimates are within a factor of three of the active surface-area, particularly at higher concentrations. In workplace environments, aerosol surface-area concentrations can be expected to span up to five orders of magnitude; thus, surface-area estimates may be suited to initial or preliminary appraisals of occupational exposure concentrations.

Although such estimation methods are unlikely to become a long-term alternative to more accurate methods, they may provide a viable interim approach to estimating the surface area of nanometer aerosols in the absence of precise measurement data. Additional research is needed on comparing methods used for estimating aerosol surface area with a more accurate aerosol surface area measurement method. NIOSH is conducting research in this area and will communicate results as they become available. In the interim, NIOSH welcomes additional information and input on this topic.

B. Proposed sampling strategy

Currently, there is not one sampling method that can be used to characterize exposure to nanosized aerosols. Therefore, any attempt to characterize workplace exposure to nanoparticles must involve a multifaceted approach incorporating many of the sampling techniques mentioned above. Brouwer et al. [2004] recommend that all relevant characteristics of nanoparticle exposure be measured and a sampling strategy similar to theirs would provide a reasonable approach to characterizing workplace exposure.

The first step would involve identifying the source of nanoparticle emissions. A CPC provides acceptable capability for this purpose. **It is critical to determine ambient or background particle counts before measuring particle counts during the manufacture or processing of the nanoparticles** involved. If a specific nanoparticle is of interest (e.g., TiO_2), then area sampling with a filter suitable for analysis by electron microscopy should also be employed. Transmission electron microscopy (TEM) can identify specific particles and can estimate the size distribution of the particles.

Once the source of emissions is identified, aerosol surface area measurements should be conducted with a portable diffusion charger and aerosol size distributions should be determined with an SMPS or ELPI using static (area) monitoring. A small portable surface area instrument could be adapted to be worn by a worker, although depending on the nature of the work, this may be cumbersome. Further, losses of aerosol with the addition of a sampling tube would need to be calculated. The location of these instruments should be considered carefully. Ideally they would be placed close to the work areas of the workers of interest, but other factors such as size of the instrumentation, power source, etc., should be considered.

Lastly, personal sampling using filters suitable for analysis by electron microscopy should be employed, particularly if measuring exposures to specific nanoparticles is

of interest. Electron microscopy can be used to identify the particles, and can provide an estimate of the size distribution of the particle of interest. The use of a personal cascade impactor or a respirable cyclone sampler with a filter, though limited, will help to remove larger particles that are not of interest, allowing for a more definitive determination of particle size.

Using a combination of these techniques, an assessment of worker exposure to nanoparticles can be conducted. This approach will allow a determination of the presence and identification of nanoparticles, and the characterization of the important aerosol metrics, providing a reasonable estimate of exposure can be achieved. This approach is not without limitations, however. It largely relies on static or area sampling, which will hamper interpretation and increase the inaccuracy of the exposure estimate.

Exposure Control Procedures

Given the limited information about the health risks associated with occupational exposure to engineered nanoparticles, precautionary work practices should be tailored to the processes and job tasks in which exposure might occur. **For most processes and job tasks, the control of airborne exposure to nanoparticles can most likely be accomplished using a wide variety of engineering control techniques similar to those used in reducing exposures to general aerosols** [Ratherman, 1996; Burton, 1997]. To ensure that the appropriate steps are taken to minimize the risk of exposure, a risk management program should be implemented. Elements of such a program should include the education and training of workers in the proper handling of nanomaterials, the criteria and procedures for installing engineering controls (e.g., exhaust ventilation) at process locations where exposure might occur, and the development of procedures describing the types of personal protective equipment (e.g., clothing, respirators) that should be used and when it should be worn.

A. Engineering controls

In general, control techniques such as source enclosure (i.e., isolating the generation source from the worker) and local exhaust ventilation systems should be effective for capturing airborne nanoparticles, based on what is known of nanoparticle motion and behavior in air. Ventilation systems should be designed, tested, and maintained using approaches recommended by the American Conference of Governmental Industrial Hygienists [ACGIH, 2001]. In light of current scientific knowledge regarding the generation, transport, and capture of aerosols, these control techniques should be effective for controlling airborne exposures to manometer-scale particles [Seinfeld and Pandis, 1998; Hinds, 1999].

Dust collection efficiency of filters

Current knowledge indicates that a well-designed exhaust ventilation system with a high-efficiency particulate air (HEPA) filter should effectively remove nanoparticles [Hinds, 1999]. NIOSH is conducting research to validate the efficiency of HEPA filter media used in environmental control systems and in respirators in removing nanoparticles. As results of this research become available, they will be posted on the NIOSH web site. Filters are tested using particles that have the lowest probability of being captured (typically around 300nm in diameter). Collection efficiencies for smaller particles should exceed the measured collection efficiency at this particle diameter [Lee and Liu, 1982]. The use of a HEPA filter must also be coupled to well-designed filter housing. For example, if the filter is improperly seated, nanoparticles have the potential to bypass the filter, leading to filter efficiencies much less than predicted [NIOSH, 2003]. An unventilated process enclosure that is effective in controlling the emission of larger particles may not be effective in controlling nanoparticles because of their greater ability to penetrate small gaps and the nontraditional measurements needed to evaluate effectiveness of control.

B. Work practices

The incorporation of good work practices in a risk management program can help to minimize worker exposure to nanomaterials. Examples of good practices include the following:

- Cleaning work areas at the end of each work shift (at a minimum) using HEPA vacuum pickup and wet wiping methods. Dry sweeping or air hoses should not be used to clean work areas. Cleanup and disposal should be conducted in a manner that prevents worker contact with wastes and complies with all applicable federal and State, and local regulations.
- Preventing the storage and consumption of food or beverages in workplaces where nanomaterials are handled.

- Providing hand-washing facilities and encouraging workers to use them before eating, smoking, or leaving the worksite.
- Providing facilities for showering and changing clothes to prevent the inadvertent contamination of other areas (including take-home) caused by the transfer of nanoparticles on clothing and skin.

C. Personal protective clothing

Currently, no guidelines are available on the selection of clothing or other apparel for the prevention of dermal exposure to nanoparticles. Published research has shown that penetration efficiencies for eight widely different fabrics (including woven, non-woven, and laminated fabrics) against 0.477 μm particles range from 0.0 percent to 31 percent, with an average of 12 percent [Shalev et al., 2000]. Penetration efficiencies for nanoparticles have not been studied. However, even for powders in the macro scale, it is recognized that skin protective equipment (i.e., suits, gloves acid other items of protective clothing) is very limited in its effectiveness to reduce or control dermal exposure [Schneider et al., 2000]. In any case, although nanoparticles may penetrate the epidermis, there has been little work to suggest that penetration leads to disease, and no dermal exposure standards have been generated.

Existing clothing standards already incorporate testing with nanometer-sized particles and therefore provide some indication of the effectiveness of protective clothing with regard to nanoparticles. For instance, ASTM standard F1671–03 specifies the use of a 27nm bacteriophage to evaluate the resistance of materials used in protective clothing to penetration by blood-borne pathogens [ASTM Subcommittee F23.40, 2003].

D. Respirators

In the hierarchy of controls, respirators may be necessary when engineering and administrative controls do not adequately keep worker exposures to an airborne contaminant below a regulatory limit of an internal control target. Currently, there are no specific exposure limits for airborne exposures to engineered nanoparticles although occupational exposure limits (e.g., OSHA, NIOSH, ACGIH) exist for larger particles of similar chemical composition. Preliminary scientific evidence indicates that nanoparticles may be more biologically reactive than larger particles of similar chemical composition and thus may pose a greater health risk when inhaled.

The decision to institute respiratory protection recommended in this document should be based on a combination of professional judgment and the results of the risk assessment and risk management approach recommended in the document. The effectiveness of administrative, work practice, and engineering controls can be evaluated using the measurement techniques described in *Exposure Assessment and Characterization.* If worker exposure to nanoparticles remains a concern after instituting measures to control exposure, the use of respirators can further reduce worker exposures. Several classes of respirators exist that can provide different levels of protection when properly fit tested on the worker. Table 1 lists various types of particulate respirators that can be used along with information on the level of exposure reduction that can be expected from each and the advantages and disadvantages of each respirator type. To assist respirator users, NIOSH has published the document *NIOSH Respirator Selection Logic (RSL)* that provides a process that respirator program administrators can use to select appropriate respirators for agents with exposure limits (see *www.cdc.gov/niosh/docs/2005-100/default.html*). As new toxicity data for individual nanomaterials become available, NIOSH will review the data and make recommendations for respirator protection.

When respirators are required to be used in the workplace, the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134) requires that a respiratory program be established that includes the following program elements: (1) an evaluation of the worker's ability to perform the work while wearing a respirator, (2) regular training of personnel, (3) periodic environmental monitoring, (4) respirator fit testing, and (5) respirator maintenance, inspection, cleaning, and storage. The standard also requires that the selection of respirators be made by a person knowledgeable about the workplace and the limitations associated with each type of respirator. OSHA has also issued guidelines for employers who choose to establish the voluntary use of respirators [29 CFR 1910.134 Appendix D].

NIOSH tests and certifies respirator filters using solid (NaCl) or liquid (DOP) particles that are nominally 0.3 μm in diameter to determine the filter's collection efficiency at 95 percent to at least 99.97 percent. Particles of this size are considered to be the most penetrating particle size [TSI, 2005; NIOSH, 1996]. Particles larger

than 0.3 μm are collected most efficiently by impaction, interception, and settling. Particles smaller than 0.3 μm are collected most efficiently by diffusion or electrostatic attraction. Current data indicate that the penetration of approximately 0.3 μm particles represents the worst case [Martin and Moyer, 2000]. Since nanoparticles are typically smaller than 100 nanometers they are theoretically collected more efficiently than the 0.3 μm test aerosols [Hinds, 1999]. NIOSH is conducting research to validate the efficiency of HEPA filter media used in environmental control systems and in respirators in removing nanoparticles. As results from this research become available, they will be posted on the NIOSH Web site.

Table1. Air-Purifying Particulate Respirators

Respirator type	NIOSH assigned protection factor [106]	Advantages	Disadvantages	Cost (2004 dollars)
Filtering facepiece (disposable)	10	– Lightweight – No maintenance or cleaning needed – No effect on mobility	– Provides no eye protection – Can add to heat burden – Inward leakage at gaps in face seal – Some do not have adjustable head straps – Difficult for a user to do a seal check – Level of protection varies greatly among models – Communication may be difficult – Fit testing required to select proper facepiece size – Some eyewear may interfere with the fit	$0.70 to $10
Elastomeric half-facepiece	10	– Low maintenance – Reusable facepiece and replaceable filters and cartridges – No effect on mobility	– Provides no eye protection – Can add to heat burden – Inward leakage at gaps in face seal – Communication may be difficult – Fit testing required to select proper facepiece size – Some eyewear may interfere with the fit	Facepiece: $12 to $35 filters: $4 to $8 each
Powered with loose-fitting facepiece	25	– Provides eye protection – Protection for people with beards, missing dentures or facial scars – Low breathing resistance – Flowing air creates cooling effect – Face seal leakage is generally outward – Fit testing is not required – Prescription glasses can be worn – Communication less difficult than with elastomeric half-facepiece or full-facepiece respirators – Reusable components and replaceable filters	– Added weight of battery and blower – Awkward for some tasks – Battery requires charging – Air flow must be tested with flow device before use	Unit: $400 to $1,000 Filters: $10 to $30

Elastomeric full-facepiece with N-100, R-100, or P-100 filters	50	– Provides eye protection – Low maintenance – Reusable facepiece and replaceable filters and cartridges – No effect on mobility – More effective face seal than that of filtering facepiece or elastomeric half-facepiece respirators	– Can add to heat burden – Diminished field-of-vision compared to half-facepiece –Inward leakage at gaps in face seal –Fit testing required to select proper facepiece size –Facepiece lens can fog without nose cup or lens treatment –Spectacle kit needed for people who wear corrective glasses	Facepiece: $90 to $240 Filters: $4 to $8 each Nose cup: $30
Powered with tight-fitting half-facepiece or full-facepiece	50	–Provides eye protection with full-facepiece –Low breathing resistance –Face seal leakage is generally outward –Flowing air creates cooling effect	–Added weight of battery and blower –Awkward for some tasks –No eye protection with half-facepiece –Fit testing required to select proper facepiece	Unit: $500 to $1,000 Filters: $10 to $30
		–Reusable components and replaceable filters	size –Battery requires charging –Communication may be difficult –Spectacle kit needed for people who wear corrective glasses with full face-piece respirators –Air flow must be tested with flow device before use	
Note: The assigned protection factors in this table are from the NIOSH Respirator Selection Logic.[106] When the table was prepared, OSHA had proposed amending the respiratory protection standard to incorporate assigned protection factors.[107] The Internet sites of NIOSH (www.cdc.gov/niosh) and OSHA (www.osha.gov) should be periodically checked for the current assigned protection factor values.				

E. Cleanup of nanomaterial spills

No specific guidance is currently available on cleaning up nanomaterial spills. Until relevant information is available, it would be prudent to base strategies for dealing with spills on current good practices, together with available information on exposure risks and the relative importance of different exposure routes. Standard approaches to cleaning up powder and liquid spills include the use of HEPA-filtered vacuum cleaners, wetting powders down, using dampened cloths to wipe up powders and applying absorbent materials/liquid traps. As in the case of any material spill, handling and disposal of the waste material should follow any exiting federal, State, or local regulations.

When developing procedures for cleaning up nanomaterial spills, consideration should be given to the potential for exposure during cleanup. Inhalation exposure and dermal exposure will likely present the greatest risks. Consideration will therefore need to be given to appropriate levels of personal protective equipment. Inhalation exposure in particular will be influenced by the likelihood of material re-aerosolization. In this context, it is likely that a hierarchy of potential exposures will exist, with dusts presenting a greater inhalation exposure potential than liquids, and liquids in turn presenting a greater potential risk than encapsulated or immobilized nanomaterials and structures.

Research

NIOSH has developed a strategic plan for research on several occupational safety and health aspects of nanotechnology. The plan is available at *www.cdc.gov/niosh/topics/nanotech/strat_plan.html.* Review and feedback on the plan is welcomed.

** Code of Federal Regulations. See CFR in references.*

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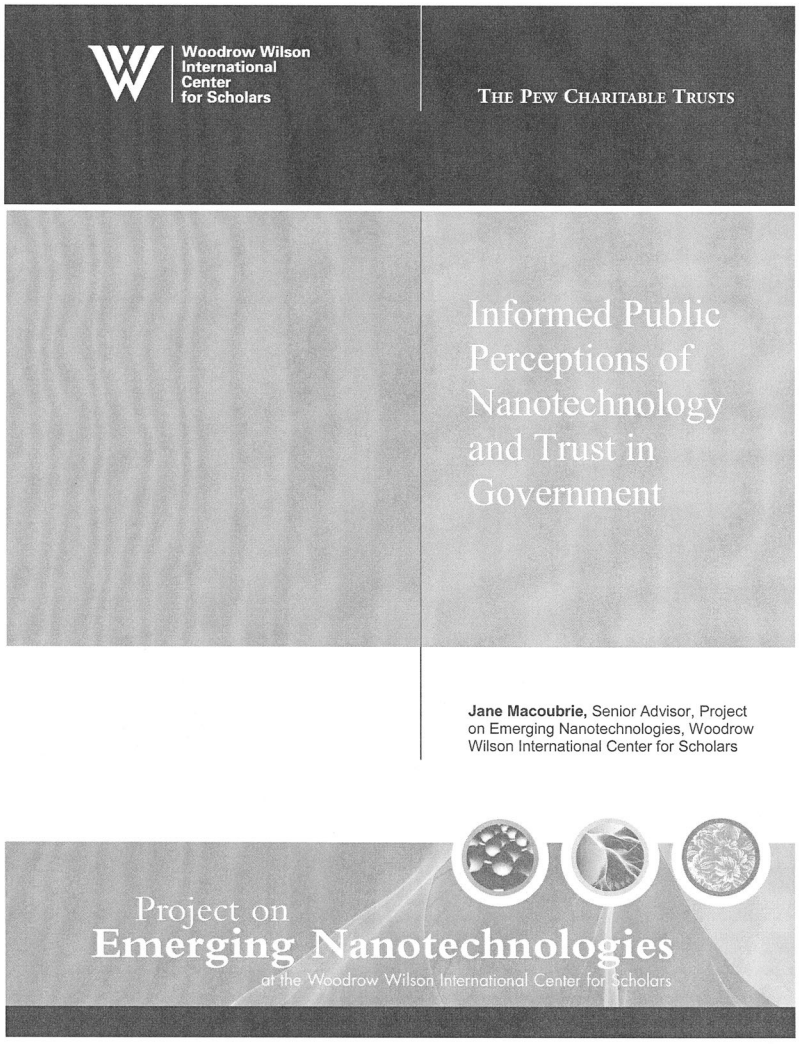
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Informed Public Perceptions of Nanotechnology and Trust in Government
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Project on
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Informed Public Perceptions of Nanotechnology and Trust in Government

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INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT

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INTRODUCTION

Nanotechnology is science's next big thing. It's the tiny world of controlling matter at the scale of one billionth of a meter, or less than one-100,000th the width of a human hair. Researchers are exploring ways to see and build at this scale, reengineering familiar substances like carbon and gold to create new materials with novel properties and functions.

In just a few short years, nanotechnology has catapulted from being a specialty of a few physicists and chemists to a worldwide scientific and industrial enterprise. The National Science Foundation predicts that the global marketplace for goods and services using nanotechnologies will grow to $1 trillion by 2015, and there are already over 500 products being sold that claim they are made with nanoscale or engineered nanomaterials. These include products like self-cleaning windows, automobile paint, sunscreens, and tennis rackets. In the future, a marriage of nano and biotechnology will likely create a whole new generation of drugs, biomedical devices, and other solutions to some of our most challenging medical problems.

But little is known about the technology's possible health and environmental implications. The federal government is just beginning to develop regulatory approaches specific to nanotechnology applications and production. At this critical juncture, it is important that leaders from industry, government, the science and engineering community, and other sectors develop a better understanding of what the public wants and expects in terms of the oversight of these new and emerging technologies.

This report, "Informed Public Perceptions of Nanotechnology and Trust in Government," could not come at a more propitious time. It provides an in-depth look at what Americans know and do not know about nanotechnology. It offers a view of the nano applications and products people think are most important. It examines who Americans trust most to manage nanotechnology's potential risks. And it highlights what particular concerns citizens may have about nanotechnology's use.

For me, the most important message from this report is that a lack of information—about nanotechnology-based products, about their possible health and environmental implications, and about the oversight processes designed to manage risks—breeds public mistrust and suspicion. This report shows that in the absence of balanced information, people are left to speculate about the possible impacts of nanotechnology. They often draw on analogies to past technologies, many of which may be misleading, such as asbestos, dioxin, Agent Orange, or nuclear power.

Consumers want more information to make informed choices about nanotechnology's use, and they strongly support more research and safety testing before products go to market. When asked whether they felt voluntary standards for industry would be sufficient to manage the potential risks of nanotechnology, 55 percent of study participants said that mandatory government controls are necessary. An additional 33 percent were unsure whether voluntary standards would be sufficient. Government and

industry need to realize that while voluntary measures may be pursued in the short term, they may not assuage public concerns over the long term.

After taking part in the issue groups we conducted, half the participants felt mostly or quite positive about nanotechnology, and 32 percent remained neutral. Traditionally, the public is willing to accept risks associated with new technologies if there is clear evidence of early, significant new benefits like low cost, highly efficient solar energy or a breakthrough treatment for Alzheimer's disease.

For nanotechnology, those significant benefits are still largely a promise. Until they are delivered, expect a certain degree of public skepticism about the next big thing.

David Rejeski
Director, Project on Emerging Nanotechnologies
Washington, DC
September 2005

Executive Summary

This report presents results of a study, conducted May through June of 2005, on the public's perceptions of government, nanotechnology, and regulation. The study was designed in response to a number of questions that emerged from a 2004 study, which found low levels of public trust in government to manage potential risks associated with nanotechnology. In this study, we wanted to learn more about why this low level of trust exists. Is there simply a general public mistrust in government or is it related to individual government agencies or particular applications of nanotechnology? More specifically, we wanted to find out what steps government and industry could undertake to improve trust.

Using a highly structured research approach, we formed groups consisting of private citizens in Cleveland, Dallas, and Spokane, and provided them with balanced, clearly written information on nanotechnology and on U.S. regulatory and policy-making bodies relevant to nanotechnology. The information packets included four sets of briefing materials to explain applications of emerging nanotechnologies, including such areas as consumer and personal product applications and products created by the convergence of biotechnology and nanotechnology.

Our findings suggest the following general public perceptions, which are detailed in the body of the report and presented in table format in the Appendix.

- **Major Benefits Are Anticipated.** The top two anticipated benefits from nanotechnology are major medical advances and improved consumer products, which accounted for 31% and 27% of all the benefits identified, respectively. General technological progress was also seen as a significant benefit, as were advances in environmental protection, lower cost energy, and improved food and nutrition.

  "It sounds like a great idea. It can help everything."

- **Public Wants To be Included.** The need for a voice for the public and the lack of information available to consumers about technology decision-making were strong threads throughout the study. Participants were concerned about the existence of hundreds of nanotechnology-enabled products in the marketplace and the expenditure of billions of dollars of taxpayer money on nanotech R&D without public involvement. Participants presented an overarching desire to both be informed and to have a role in decision-making. "We need to be informed," demanded one participant while another stated that "government should not be making these decisions alone," especially as it relates to medicine and to food.

  "One of the drawbacks of nanotechnology is that there are going to be a lot of people out there who are scared because they don't know what it is, and are going to slow the technology down."

- **Lack of Support for a Ban on Nanotechnology Products.** One non-governmental group has advocated that new nanotechnology products be banned until further study of the potential risks. After learning about

nanotechnology and its applications, 76% of respondents believe "a ban is overreacting."

- **High Demand for Effective Regulation.** The majority of study participants felt that voluntary safety standards applied to industry would not be sufficient to manage the potential risks associated with nanotechnology; 55% said government control beyond voluntary standards is necessary, while 33% were unsure. Only 11% felt voluntary standards would be adequate. Even given their regulatory concerns, 50% felt positive or quite positive after learning about nanotechnology and the differing roles of the regulatory agencies, while 32% remained neutral.

"Nanotechnology can be good, if regulated properly."

- **Low Public Trust in Government.** As in the earlier study, low trust in government to manage technology-related risks was still prevalent. It appears to be related, first, to specific regulatory agencies and other entities of government, and second, to specific applications of nanotechnology. Trust in regulatory agencies seems to reflect past history with certain categories of products, e.g., the Food and Drug Administration's difficulty with the drug Vioxx. Public trust was lowest vis-a-vis the Congress and the White House. Study participants felt political pressure has in the past interfered with protections for public safety. Regulatory agencies were thought to be trying to do their job to ensure public safety, but limited by outside pressure from providing appropriate levels of protection.

"Regulators are affected by politicians... Politicians are influenced by lobbyists."

- **Suspicions of Industry.** Past safety issues with specific products, ranging from drugs to genetically engineered crops, have led to a widespread perception that industry pushes products to market without adequate safety testing, makes too many errors affecting people's health, and puts its own motives ahead of consumer safety. In general the participants felt there are "unscrupulous risks taken by the medical community," and overall there exists "a race with too many mistakes."

"I'm all for it if it makes my life easier, but it is like Vioxx – the world is in a rush, rush, rush, to get it out there."

- **Specific Recommendations on How to Improve Trust.** There was a surprising degree of agreement among participants on how government and industry could improve trust. These were: (1) through more testing before products were introduced and (2) the provision of more information to the public.. One participant observed "[there is] a past history of failed precautions," and most participants supported a more "thorough investigation before [product] release."

- **Media Influence is Presently Low.** Study participants knew little about nanotechnology prior to the study. Of those who had heard of it from one source, 22% said it was from public television or radio, and 20% indicated they had heard about nanotechnology from another person (word-of-mouth). Popular media channels seem to be having little impact on awareness, while for most, commercial news media is not a primary source of information.

Background

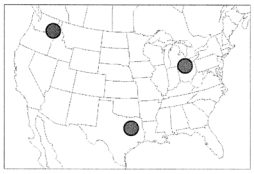
In 2004, the National Science Foundation provided funding for two separate explorations of citizen perceptions of nanotechnology. First, a national survey explored issue framing, trust in government to manage risks, and expectations of benefits versus risks from nanotechnology. Awareness of nanotechnology, attitudes towards it, and the present effect of science fiction films and novels such as Michael Crichton's recent book *Prey* also were investigated (Cobb & Macoubrie, 2004).

Second, a separate study was designed to investigate the reactions of informed citizens. This study used experimental issue groups (EIGs) where citizens in three different cities were provided with background materials on nanotechnology and scenarios depicting possible developments projected for nanotechnology. Several forms of data were collected from the EIGs, including questionnaire data on attitudes towards nanotechnology, levels of concern for risk, trust in government and industry to manage risks, individual level reflections and insights, and demographic data for the participants (Macoubrie, in press). Major findings of the 2004 studies:

- The national survey, which sampled 1,250 people, found high interest in anticipated benefits from nanotechnology. Many people had only heard the word nanotechnology, however, little knowledge has penetrated through the media to the general public.
- The highest interest was in medical applications, particularly to target disease without invasive surgery, collateral damage, or side effects. However, in two regions of the country (West Coast and Midwest), these applications also evoked the lowest trust in government to manage the risks.
- The public was not at all certain benefits would exceed risks. In fact, 22% believed risks would exceed benefits, while 38% expected risks and benefits to be about equal; 40% believed benefits would exceed risks.
- In the experimental groups that were conducted involving 152 people, 95% of the participants expressed little or no trust in government to effectively manage the possible risks associated with nanotechnology. In the national survey, 95% of those surveyed did not trust industry leaders to effectively manage any risks. The similarity of these results was striking.
- In the 2004 experimental study examining concerns about nanotechnology and reasons for them, concerns were dominated by experiential knowledge. Rather than true unknowns, possibilities that neither scientists nor citizens can predict, concerns were based on knowledge of past technological "breakthroughs" from which significant downsides later emerged.
- The public did not seem to be fearful of nanotechnology itself, but is highly aware of past failures to gauge and manage risks found to be associated with other new technologies.
- World military and "evil doer" risks were mentioned the most, followed by concerns about long-term health risks and environmental impacts.
- Finally, higher education (college degree or higher) was related to low trust in government to manage any risks. No other demographic variable showed any significant link.

Overview of this Study

A more detailed description of the study design is provided in the Appendix. This section provides a sketch of the methods in areas that may be of most interest to readers. To study informed citizens' perceptions and attitudes, information was provided to participants about existing and emerging nanotechnology applications in areas such as consumer products, medicine, and agriculture. One group received materials that discussed the anticipated convergence of nanotechnology and biotechnology and its uses to enhance the human body. In all, 12 groups with a total of 177 participants were gathered together in 3 different locations: Spokane, Washington; Dallas, Texas; and Cleveland, Ohio.



Following known best practices of science journalists, the background materials were developed to present a balanced view of known and projected applications of nanotechnology. Brief information also was included on the roles of six regulatory agencies, as well as Congress and the White House, involved (or potentially involved) in nanotechnology oversight. The materials were reviewed by scientists and regulators for accuracy, balance, and clarity and were written to be understandable by a lay audience. Materials focused on conveying known facts and the reasoning about important issues rather than merely stating opposing positions. The data analysis reported here was conducted by Dr. Jane Macoubrie.

Study pre- and post-test questionnaire, informational materials, and additional details of the study methodology are given in the Appendix of this report. Study participants were recruited to be representative of demographics in the 3 locations chosen for the study. The primary characteristics of the study participants relative to the 2000 Census are shown below.

	2005 Study Participants									
	Political Affiliation	Gender %		Race %				Mean Income	Mean Age	EDU %
		M	F	Cauc	Afr.Am.	Hisp./ Latino	Native American & Other			
Study Sample	R=30% D=37% Ind=25% Other=8 %	49.2	49.2	58.8	20.3	14.7	5.1		43	HS=22* SC=26 TRD/CERT=10 CD=23 >CD16
2000 US CENSUS		49	51	77	13	4.2		50K	35.3	HS=27 SC=21 CD=26 >CD=9

EDU: HS = high school diploma, SC = some college, TRD = trade or certificate training beyond HS, CD = college degree, >CD = education beyond 4 year degree. *Less than HS = 2.3%. Missing data = 1.1%.

Results of this study are from an analysis of three forms of data:

1) answers to survey questions in pre- and post-test questionnaires,
2) individual-level data provided in response to opportunities to privately express areas of concerns and benefits, prior to group discussion, and
3) group discussion of concerns, benefits, and perceptions of regulatory agencies.

Pre-test survey questionnaires were administered prior to the study. After reading the informational materials, individuals then gave responses to 'concerns' and 'anticipated benefits' of nanotechnology, discussed specific issues in their group, and finally, completed a post-study questionnaire. Some questionnaire items were included in both pre- and post-test; others were only asked in post-test, as appropriate.

Full Study Results

This section of the report summarizes the findings and uses examples of participants' comments or statements of concerns/benefits to illustrate the results. Data tables of full results are given in the Appendix.

General Attitudes and Knowledge

- **Low Awareness of Nanotechnology:** As in the 2004 studies, most people participating in the study had little initial awareness of nanotechnology. Answering the pre-study questionnaire, 54% professed to know almost nothing, 17% felt they knew something about nanotechnology, and 26% said they knew a little. Asked if nanotechnology is predicted to become another industrial revolution (true), 75% said "don't know" and 24% answered "true." [See Tables 1 and 2, Appendix]

- **Varied Sources of Knowledge:** Study participants were also asked about the sources of their information on nanotechnology, if they had any prior knowledge. When respondents identified only one source of knowledge, 22% said they had heard about nanotechnology from public television or radio, and 20% said they had heard about nanotechnology from another person. 14% had heard of nanotechnology from commercial television or radio news, 10% from science fiction, 8% from magazines and 8% from newspapers. If respondents had heard of nanotechnology from two sources, 28% mentioned magazines, 17% hearing from another person, 14% from science fiction, 11% from trade journals, and another 11% from public television or radio. [See Table 3, Appendix]

- **Generally Positive Attitude towards Nanotechnology:** Initial attitudes towards nanotechnology prior to the study were investigated by asking "are you quite positive, mostly positive, neutral, mostly negative, or don't know concerning your feelings about nanotechnology?" Initially, 38% were neutral, 13% were mostly positive, 41% answered "don't know," and less than 9% were either quite positive or mostly negative. After the study, 50% were mostly or quite positive, 32% remained neutral, 13% were mostly or quite negative, and 3% answered "don't know." [See Table 4, Appendix]

- **Benefits will Exceed Risks:** Perceived risks of nanotechnology versus nanotechnology's benefits were also tested in pre- and post-study questionnaire. After the study, 41% said the benefits should exceed the risks, 30% believed the risks and benefits would be about equal, 15% expected risks to exceed benefits, and 14% answered "don't know." [See Table 5, Appendix]

- **Little Support for a Ban:** After they had learned about nanotechnology, participants were asked: "Should nanotechnology be banned until further study of possible risks?" 76% of the respondents said "a ban is overreacting." An additional 16% said "don't know;" 8% supported a ban of new nanotechnology products. [see Table 6, Appendix]

Respondents' Interests in Nanotechnology Benefits

After reading informational materials on one of the four emergent applications areas of nanotechnology, study participants were asked to identify up to 5 areas of highest interest regarding the potential benefits of nanotechnology. These areas were written individually by study participants on a 5"x7" card, one benefit listed per card. The benefits of interest were clustered together as types of benefits (e.g., "treat cancer," "reduce overuse of antibiotics," "a cure for Alzheimers," "could lead to a cure for HIV/AIDS," are grouped in the benefit category of major medical uses). See the Appendix for more information on the analytic method used to summarize concerns and benefits.

1. **Medical Applications of Greatest Interest:** Study participants named as the top type of benefit major medical advances possible through nanotechnology (31% the of benefits identified). This included a wide range of possible applications from new diagnostic methods to treatments for cancer and diabetes.

2. **Better Consumer Products:** The second most frequently mentioned benefit group (27%), the consumer product category, contains potential benefits like "less toxic paint coatings," "toothpaste to fill cavities," "make life easier," "trash bags that biodegrade" and "stain resistant clothing."

3. **General Progress.** Benefits related to general progress account for 12% of benefits identified (general advancement - 5%, human race progress - 2%, and general knowledge advancement - 5%).

4. **Environmental Protection:** Environmental protection ranked fourth (8%) in benefits mentioned and includes such things as "less contaminated water," "stop damage to the planet," and "reduce waste, use less materials."

5. **Safer and Better Food:** Food and nutrition benefits, the 5th most frequently named benefit (6%) includes "safer food," (from smart packaging), "more nutritious food," and the ability to "feed the world."

6. **Energy, Economy, Electronics**: Energy benefits, the economy, and improved electronics and computing each garnered 4% of benefits envisioned.

7. **Benefits to Soldiers, Security.** Military uses and national security were mentioned in 3% of benefit comments.

N = 349 benefits named by 177 participants	*Percentage*
Major medical uses	31
Consumer products	27
General progress*	12
Environmental protection	8
Food and nutrition	6
Economy, jobs	4

Energy	4
Electronics, computers	4
Military uses and national security	3
Advancing international welfare	1

*Knowledge advancement 5%, Advance society 5%, Human race progress 2%

Specific Concerns About Nanotechnology

Study participants were invited to identify areas of concern separately from benefits. Areas of concern were written individually by study participants on a 5"x7" card, one per card, and later, categorized as they fell cumulatively into particular types of concern.

- **High Level of Concern about Unknowns, Regulation, and Health Risks:** The three top-ranking concerns -- true unknowns, regulation, and human health risks – accounted for almost 40% of the total concerns mentioned. The true unknowns label applies to concerns identified where outcomes and effects cannot be predicted by anyone, including nanoscientists. This category includes concerns such as "unknown risks and consequences," "unintended uses," "how our manipulation will effect natural laws," and "unpredictability if nano follows its own natural laws."

""Keep looking, but be careful what you're looking at. We've got to keep our curiosity up… and be aware of what the consequences can be."

- **Long-term Effects:** Also high on the list of concerns were those relating to the need to better understand and mange potential long-term effects. Concerns identified included "thorough investigation before release," "standards...past history of failed precautions," "you aren't talking about the long-term effects...why not?" and "should have substantial research on long-term effects."

"What effect does it have on the environment? What happens if they don't break down? How do we get rid of them? We don't want to find out in 20 years that it causes cancer."

- **Human Health Risks are Important:** Human health concerns included statements such as "cell effects that lead to cancer, like in the past," "in medical uses it could go where it shouldn't," "immune system responses," "lab-created parts that just fail later," and "medically untested cures."

- **Concerns Affected by Past Problems:** Examples of past regulatory, environmental, and human health errors, given to support concerns in several categories, included Vioxx, Viagra, Phen Fen (dietary pills), DDT, asbestos, nuclear power, lead in gasoline, jet fuel contaminating military bases, and genetically-engineered foods.

"It's like nuclear power. It's a great concept but what do you do with the waste products?"

- **Playing God:** Playing God and messing with nature includes "unnatural products that cause harm," "trying to outthink God...it won't work," "natural is better," "don't mess with nature," "leave DNA alone, don't play God," and "as a consumer, I want purity, not chemicals." While this was a concern mentioned individually by 5% of respondents, this concern was reiterated in group discussion by a small but vocal minority.

- **The Need for Effective Regulations:** The regulatory category includes concerns for both ineffective and potentially over-restrictive regulations. Participants spoke about "politics getting into regulation," "who regulates the regulators, like with biopharming," "lack of regulation during development," "must be regulated sufficiently," "that government can be manipulated to get the effect desired," "if too many regulate, nothing will get done," as well as "whether it will be over-regulated" and "over regulation leaving U.S. in the dust, like with stem cells."

- **Military Uses and Abuses:** Concerns over military uses ranged from "bad guys with progressive tools," to "keep our soldiers safer," "use to fight terrorism," and include concern about "international competition with negative effects," as well as "a new arms race" and "no military applications...I don't' trust this."

"[Nanotechnology] could create weapons worse than nuclear."

- **In My Food?:** Nanotechnology's use in food products, packaging, and agriculture led to food chain concerns, including "long term consumption of nano food," "adulterated field crops," "natural agriculture and animals," "foods that metabolize to worsen health," "biopharming in the wrong hands could be disastrous," and "using live people for experiments with FDA approval."

"I have reservations as far as its use in food, animals, in the chain that we eat."

- **Consumer Information:** Consumer knowledge and information concerns included "what say will the public have?" "government alone should not be making these decisions," "who gets a say in regulation?" "lack of knowledge & disclosure to users," "we should know when food is affected by nano and be told the risks," and "we need to be informed when nanotechnology is in something like cosmetics."

- **People Centered Goals:** People centered goals for progress include concerns like "can we trust government to make decisions for the good of people and not just $$," "moral implications of nano medicine...extent of its use and by whom?" and that we "should study moral and social guidelines more."

"We're gonna be killed or cured."

N = 426 concerns identified by 177 participants	*Percentage*
True unknowns	13
Regulatory concerns	13
Human health risks	13
Testing and research for safety	12
Effect on environment	10
Food & food chain concerns	7
Industry irresponsibility	7
Privacy	6
Military uses, international political instability	6
Playing God, messing with Mother Nature	4.5
Economic access & education	4

Consumer knowledge & information	3
People centered goals for progress	2
Taxpayer cost of development	1
Fearful people stopping good	1
Mistrust of government in general	1
Social upheaval & adjustment	.5

Trust in Regulatory Agencies, Political Entities, and Industry

One purpose of this study was to discover more about the sources of low trust in government in relation to nanotechnology. The 2004 study had found low levels of trust, largely based on experience with earlier technologies, in which situations arose where too little knowledge of products later led to environmental and human health problems. Examples given in 2004 included asbestos, dioxin, lead paint, Prozac accumulating in bodies of water, PCBs, and Agent Orange.

To determine if low trust in government is related to any specific entity, questions in both the entry survey questionnaire and the post-test were asked in relation to different regulatory agencies: "Even if there are risks with nanotechnology, I trust the (.....) to effectively manage these risks." The agencies and political entities tested for association with low trust were the Congress, White House, Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Centers for Disease Control (CDC), Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), and United States Department of Agriculture (USDA). Congress and The White House were included simply to include a wide variety of political entities that might affect nanotechnology policy and regulation. After participants had read about nanotechnology applications and regulatory responsibilities, as well as completed other parts of the study, the trust questions were asked again in order to measure trust in regulatory entities related to nanotechnology.

Results concerning trust in government indicate that low trust is related specifically to (1) particular federal agencies, and (2) to specific applications of nanotechnology. There also were a number of other interesting findings:

- **Low Initial Awareness of the Role of Government Agencies:** In the pre-test (the questionnaire given prior to reading informational materials on nanotechnology and regulatory agencies), 33% to 46% said they did not know if the FDA, EPA, USDA, White House, or Congress, etc., would effectively manage risks. This uncertainty changed in the post-test, after participants received information on both nanotechnology and regulatory responsibilities.

"I found it interesting so many government agencies are potentially responsible [for nanotechnology]. With so many agencies, bureaucracy hinders the process because everybody is fighting over who is responsible."

- **Low Trust in Congress and the White House:** Congress and the White House received lower initial trust responses compared to regulatory agencies: 40% and 38% 'disagree' or 'strongly disagree' these entities could be trusted to

effectively manage any risks, while 25% and 29%, respectively, agreed or strongly agreed that these entities were trustworthy.

- **Regulatory Agencies Fare Better:** Regulatory agencies received higher levels of agreement that they would effectively manage any risks: 37% initially trusted OSHA, 38% trusted CPSC and 39% of participants initially agreed they would trust CDC to effectively manage risks.

- **More Information Changed Trust Levels:** After learning about nanotechnology and regulatory agency responsibilities, many study participants in the post-test moved away from the "don't know" category. The directions of these changes, however, varied.

- **Worse News for the Congress:** In the post-test answers, Congress fared worst on the question of trust: 63% disagreed or strongly disagreed that Congress would effectively manage any risks (27% agreed or strongly agreed that Congress would not; 10% said "don't know"). In the post-learning answers, the White House fared better than Congress. Still, 43% of participants disagreed or strongly disagreed that the White House would effectively manage any risk (31% trusted the White House, in the post test, while 12% said "don't know").

- **Trust in EPA, OSHA, CPSC, and CDC Increased:** Trust in a number of agencies rose after study respondents knew more about their responsibilities and about nanotechnology. 46% trusted CPSC; 45% trusted EPA; 50% trusted CDC; 46% trusted OSHA. Trust in OSHA is notably ambivalent in comparison to other agencies, however, as 40% also do not trust that agency to effectively manage any risks.

- **Trust in FDA and USDA Not as Certain:** Agencies whose trust figures were lower after citizens learned about nanotechnology and regulatory responsibilities were FDA (43% did not trust and 13% don't know, while 44% do trust) and USDA (45% did not trust, 16% don't know, while 39% do trust). In the discussion part of the study, concerns about FDA regulations were raised in all 12 groups. "FDA should not let companies put all kinds of stuff in food" commented one respondent. Medical products were frequently given as examples where important risks emerged years after product release. In addition, participants spoke about their low trust in FDA as related to perceived influence from Congress and industry, which they believed could undermine regulatory protections. Taken together, the evidence points to FDA, and to a lesser extent, USDA, as significant nanotechnology regulatory concerns for citizens.

Explaining more about public trust are the comments participants made about this issue in the group discussions. The group moderator synthesized these comments about the regulatory agencies in this conclusion: "Many participants trust the average agency employee to be honest and hardworking, but see the upper levels of agency management to be susceptible to political pressure and political control." Despite mixed-to-negative views of some regulatory agencies, a

substantial proportion of participants also expressed that they "are glad the agencies exist, acknowledge their past contributions to society, and felt that the agencies at the very least are doing the best they can."

In the individual-level concerns expressed, participants further illuminated their feeling that politics negatively affects public safety. That "legislators try to undo environmental protections," is one example.

Strategies to Increase Public Trust in Nanotechnologies

We also asked survey questions concerning ways government could work to increase public trust and whether people believed industry self-regulation would be sufficient (see Appendix, Tables 9, 10, and 11, respectively).

- **Voluntary Standards Insufficient:** The majority of study participants felt that voluntary standards applied by industry would not be sufficient. 55% said government control beyond voluntary standards is necessary, while 33% were unsure; 11% felt voluntary standards would be adequate.

"Voluntary standards, possible risks, and bureaucrats: That's a red flag for me."

- **More Safety Testing and Information Needed:** There was strong agreement among participants concerning the most important ways government and industry could work to increase public trust. 71% of top choices were for increased safety tests before products go to market, supplying more information to support informed consumer choices, and demonstrating how current regulation is sufficient to protect the environment and workers.

- **Tracking Risks of Products on the Market:** "Better tracking risks related to products already on the market" was the 4th-highest ranking choice for ways both government and industry could work to increase public trust.

Interest in Public Information and Education

A strong thread of concern about public information is woven throughout the survey and group discussion data.

- **Consumers Want More Information:** Increasing consumers' ability to make informed choices was the 2nd most preferred way our respondents said either government or industry could help to enhance the public' trust. In other words, public information is a highly preferred mechanism either industry or government should employ to increase public trust.
- **Lack of Information Breeds Suspicions:** Group discussion stressed the lack of public information over and over again. The group facilitator noted that, "The lack of public notification and information about the market status of nanotechnology products was also a major concern of these participants...The public not getting enough information is viewed as an integrity issue since it creates a suspicion of government lying and cover-ups. A strong minority opinion held that it is the public's

responsibility to get involved and educate themselves...The key element to building trust between regulatory agencies and the public is open access to information, as well to separate the regulatory process from political control."

- **No Information on Long-term Effects:** The moderator observed that "Participants were disturbed that so little information about long-term health effects of nanotechnological products, particularly consumables, is available even though products are coming out on the market. This was true of environmental effects as well." One respondent keyed in on this as a concern: "You aren't talking about the long terms effects and what is known. Why?"

References

Cobb, M. D. & Macoubrie, J. (2004). Public perceptions about nanotechnology: Risks, benefits, and trust. *Journal of Nanoparticle Research: An Interdisciplinary Forum for Nanoscale Science and Technology, 6* (4), 395-405.

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APPENDICIES

1. DATA TABLES, NANOTECHNOLOGY AND PUBLIC TRUST 2005

Table 1. Initial Knowledge of Nanotechnnology

How much would you say you know about nanotechnology?	Pre-Test
a lot	2.8
some	16.9
a little	26.0
nothing	54.2
Total	100.0

Table 2. Knowledge Re "Next Industrial Revolution"

"Nanotechnology is predicted to be the next industrial revolution"	Pre-test
true	24.3
don't know	75.1
Not true	.6
Total	100.0

Table 3. Sources of Knowledge on Nanotechnology

	All Sources	If Information From 1 Source	If Information From 2 Sources	If Information From 3 Sources
ads	2.9	4.1		3.6
children's TV	2.9	2.0	5.6	2.4
specials public TV or radio	17.6	22.4	11.1	17.9
commercial TV or radio news	11.2	14.3	5.6	11.9
magazines	17.1	8.2	27.8	17.9
newspaper articles	10.0	8.2	8.3	11.9
trade or professional journals	8.2	6.1	11.1	8.3
science fiction books or stories	12.4	10.2	13.9	13.1
talk with another person	16.5	20.4	16.7	13.1
Internet	.6	2.0		

school	.6	2.0		
Total	100.0	100.0	100.0	100.0

Note. Respondents were allowed to identify all relevant sources of learning about nanotechnology. The frequency with which each source type was mentioned is classifed above in relation to three classes of informed respondents.

Table 4. Attitudes in Pre- and Post-Test

	Pre-Study	Post-Test
quite positive	7.9	9.6
mostly positive	13.0	40.1
neutral	37.9	32.2
mostly negative	.6	9.6
don't know	40.7	2.8
Missing data		.6
Total	100.0	2.8

Significant change: Pearson Chi-Square=84.092, df = 24, p = .000

Table 5. Expectations: Will Benefits Exceed Risks?

	Pre-Study	Post-Test
benefits will exceed risks	15.8	40.7
risks will exceed benefits	5.1	15.3
risks & benefits equal	13.6	29.9
don't know	65.0	14.1
	.6	
Total	100.0	100.0

Table 6. Should Nanotechnology Products be Banned Until Further Study?

Should new nanotechnology products be banned for the time being?	Pre-Study	Post-Study
agree to total ban	6.2	8.5
Ban is overreacting	35.6	**75.7**
Don't know	57.1	15.8
Missing data	.1	
Total	100.0	100.0

Table 7. Trust in Regulatory Agencies and Political Entities, Pre- and Post-Test

%	CDC	EPA	CPSC	OSHA	FDA	USDA	WHITE HOUSE	CONGRESS
strongly agree	9.6 (9.6)	7.9 (6.2)	6.8 (6.2)	6.2 (9.0)	6.8 (6.2)	6.8 (6.2)	5.6 (4.5)	7.3 (2.8)
agree	29.4 (40.1)	23.2 (39.0)	29.4 (40.1)	30.5 (36.7)	24.3 (36.7)	23.7 (32.8)	23.2 (26.6)	18.1 (23.7)
don't know	42.4 (14.1)	41.8 (14.1)	43.5 (15.3)	40.1 (14.0)	42.4 (13.0)	45.8 (16.4)	32.8 (12.4)	35.0 (10.2)
disagree	14.7 (27.1)	19.8 (29.4)	15.3 (27.7)	19.2 (29.9)	19.8 (32.8)	18.1 (33.3)	26.0 (34.5)	27.1 (41.2)
strongly disagree	3.4 (9.0)	6.8 (10.2)	4.5 (9.6)	3.4 (10.2)	6.2 (11.3)	5.1 (11.3)	11.9 (21.5)	12.4 (21.5)
Missing data	0.6 (0)	(0.6) (1.2)	(0.6) (1.2)	0.6 (0)	0.6 (0)	0.6 (0)	(0.6) (0.6)	(0.6) (0.6)
*Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Note. Pre-test percentages are given first in each column; directly below are percentages of the post-test answers, in brackets (FDA 6.8% strongly agree in pre-test, 6.2%, etc.).

Table 8. Post-Test Summary Percentages, Trust in Regulatory Agencies and Political Entities

%	CDC	EPA	CPSC	OSHA	FDA	USDA	WHITE HOUSE	CONGRESS
Strongly agree or agree	**50**	**46**	**46**	**46**	**43**	**39**	**31**	**27**
Don't know	14	14	15	14	13	16	12	10
Disagree or strongly disagree	36	39	38	40	44	45	56	63
Total	100	99*	99*	100	100	100	99*	100

All percentages are rounded. *The designated percentages do not round to 100 due to a higher percentage of missing data for that entity.

Table 9. Can Industry Self-Regulation Be Sufficient?

Answer choices	% agreement
I feel government control beyond voluntary standards is necessary	55.4
I am not sure how I think about this	32.8
I feel voluntary standards would be adequate	10.7
Missing data	1.1
Total	100.0

Note. This was a post-test question only, assuming that only an informed public could give a useful answer to the question.

Table 10. Preferred Ways Government Could Increase Public Trust

Preferred Ways Government Could Increase Public Trust	Percent
increase safety tests before market	34.5
supply more product information so people can choose	24.9
show how regulatory practices are sufficient	11.9
track better the product risks in market	9.6
allow industry to be more self regulating	8.5
no top choice (multiple answers)	3.4
other (write in answers)	3.4
nothing needs to be done	2.3
be more hands off in regulating industry	1.7
Total	100.0

Note. The same answer choices were available for both industry and government, with the exception of the "hands off" answer; the opportunity to write in any other answers was also available in both cases.

Table 11. Preferred Ways Industry Could Increase Public Trust

Preferred Ways Industry Could Increase Public Trust	Percent
increase safety test before going to market	28.2
supply more information so people can choose	28.2
voluntarily use higher safety standards	19.2
track risks in market better	13.0
show how current reg practices are sufficient	6.8

nothing needs to be done	1.7
Missing data	1.7
Other (write in answers)	1.1
Total	100.0

Note. The same answer choices were available for both industry and government, with the exception of the "hands off" answer shown in Table 10; the opportunity to write in any other answers was also available in both cases.

2. Study Design

Study Method

To investigate concerns of an informed public and the effect of nanotechnology development scenarios, the study used a 3 by 4 quasi-experimental design. Quasi-experiments are field experiments in which one variable is controlled, while all others are left to vary as they naturally occur (Cook & Campbell, 1979; Shadish, Cook, & Campbell, 2002).

In each of 3 regional sites, participants were presented with one of 4 scenarios. Each scenario depicted a particular pathway for nanotechnology development, or 4 different scenarios, represented in written briefing materials. There was no expectation that stimuli such as the briefing materials might inherently cause a particular type of public response. Rather, the assumption was that participants would draw on existing values and knowledge in combination with the new information, and the conclusions reached thus could be usefully contrasted with those of the uninformed public.

A pre- and post-test survey questionnaire was used to gathered data on attitudes towards nanotechnology, trust in government to manage risks, and participant demographics. Data also was collected on individual concerns, expressed privately, as well as on anticipated benefits, in two separate steps, after participants read the briefing information. After providing information on concerns and benefits, each group also talked with each other about nanotechnology; the discussion thus forms a third source of information on participants' perceptions of nanotechnology and government.

Procedures

Study participants were brought together in quasi-experimental groups (4 experimental conditions) at each of 3 study locations. Although groups were used in the study, they were experimental groups rather than focus groups. Focus groups are essentially group interviews (e.g., Krueger, 1994), whereas individual-level data was sought for this study. Experimental groups were used for efficiency and control: individuals could read the experimental materials in their group settings to control for knowledge that might otherwise be gained between recruitment and exposure to experimental materials. Fifteen individuals representative of local demographics were recruited for each group.

Each group of participants first completed an entry or pre-test questionnaire. Individuals then read their experimental materials, and next, were asked to silently consider and record three or four concerns they might have about nanotechnology. Each concern was recorded by participants on a 5"x7" card, along with their personal reason or reasons for that concern. After time allowed to express concerns, individuals were then asked to silently consider and record the benefits of nanotechnology they most anticipated. After providing individual concerns and reasons, each group then spent about 40 minutes discussing concerns and expected benefits, and the roles of regulatory agencies. A standardized 1.5 hours was allotted to each group.

Participants

For this study, data was collected from individuals in experimental groups, where briefing materials were also distributed and read. Three different sized cities in the midwest, western, and southwestern regions of the U.S were chosen as sampling sites, both to discover attitudes that might be affected by regional economic and cultural variables, as well as to allow the sampling of a range of U.S. ethnicities, incomes, education levels, etc. Participants (N = 177) self assigned themselves randomly to the experimental conditions, without knowledge of doing so, by choosing group meeting times that fit their schedule. A professional firm conducted recruitment in the selected sites of Spokane, Washington; Dallas, Texas; and Cleveland, Ohio. (The 2004 study sites were in Raleigh-Durham, North Carolina; San Diego, California; and St. Paul-Minneapolis, Minnesota.) Recruitment lists were randomly generated telephone number lists in selected zip codes and study participants were recruited to be fairly representative of local demographics (see Table 1 for a comparison of the participant sample to U.S. Census Bureau 2000 statistics).

2005 Study Participants N = 177										
	Political Affiliation	Gender %		Race %				Mean Income	Mean Age	EDU %
		M	F	Cauc	Afr. Am.	Hisp. / Latino	Native Am. & Other			
Study Sample	R=30% D=37% Ind=25% Other=8 %	49.2	49.2	58.8	20.3	14.7	5.1		43	HS=22* SC=26 TRD/CERT=10 CD=23 >CD=16
2000 US CENSUS		49	51	77	13	4.2		50K	35.3	HS=27 SC=21 CD=26 >CD=9

Abbreviations. Political affiliation: R=Republican, D=Democrat, Ind=Independent. EDU: HS = high school diploma, SC = some college, TRD = trade or certificate training beyond HS, CD = college degree, >CD = education beyond 4 year degree. *Less than HS = 2.3%. Missing data = 1.1%.

Experimental conditions: briefing materials

The briefing materials for each of the 4 experimental conditions were one-and-one-half to four pages in length and designed to be read in less than 20 minutes. The materials were written for the study by the author and reviewed, for clarity and accuracy, by several nanoscientists with a broad understanding of the subject, as well as by naïve readers. Two critical choices were made in development of the briefing material. The

first was a decision to develop the materials as a lay-written review of knowledge, to focus on facts and evidence relevant to nanotechnology and its development. This choice was based on results of a recent British study of media coverage of science (Hargreaves, Lewis, & Speers, 2003). That study's authors concluded that journalists had contributed to public misunderstanding of science by reporting scientific controversy on childhood vaccinations, but not consistently reporting the evidence underlying the debate. This appears to have led to inaccurate British public perceptions about measles vaccinations and a purported link to autism. This link had been suggested by one study, but its results had not been replicable in subsequent studies. In this situation, the British public's understanding accurately captured the controversy as portrayed by journalists, but that understanding was ill founded.

A second important choice in developing the nanotechnology briefing materials was to explain nanoscience concepts by using metaphors that would be familiar to most people, in addition to using accurate scientific language. Using familiar metaphors is a teaching strategy that helps to make complex ideas accessible, and here, was intended to give adults with different education levels the greatest chance of absorbing the ideas. The status of nanotechnology was also represented by using many examples of current discoveries or existing applications, cited to the source in footnotes, for credibility.[1] The examples were gathered from nanoscience news sources and nanotechnology industry publications, and since nanotechnology is an international phenomenon, U.S. and international examples were used.

Condition 1 materials presented basic information and an overview of nanotechnology applications in general. Condition 1 groups thus represent the least informed individuals in this study. Individuals in Condition 2 received basic information plus specific information on medical and industrial nanoresearch, and anticipated and actual current uses such as in cancer treatment or disease diagnosis, electronics, energy production, and environmental cleanup. Condition 2 materials also noted the potential convergence of medical biotechnology and nanotechnology. Condition 1 and 2 materials were replications of the 2004 Condition 1 and 2 materials, but had updated examples of nanotechnology products and supplied information on the regulatory and political bodies' potential role in managing risks and benefits.

Condition 3 materials focused on nanotechnology in consumable products such as cosmetics, food products, agriculture, personal care products, clothing, and so forth. Condition 4 materials discussed the anticipated convergence of nanotechnology, biotechnology, and uses to enhance the human body. Those applications include biopharming (use of genetically altered field crops to produce human insulin, etc.), regeneration of spinal cord and brain cells or limbs, and to enhance human mental functioning. Condition 4 materials were similar to those used in 2004 but presented updated information.

Analyzing concerns

Concerns were expressed privately by participants after they had read the briefing materials for their experimental condition. Multiple concerns about nanotechnology were allowed per person, up to a limit of four; the total number of concerns expressed was N

= 394, or about 2 per person. Practices of rigorous qualitative analysis (Eisenhardt, 1989; Miles & Huberman, 1984; Yin, 1989) were followed to analyze concerns, which were classified by topical concern and then summarized quantitatively. Following Miles & Huberman's recommended practices for cross-case analysis, first individual-level concerns were noted sequentially in a data log, for each group; no concerns were excluded. Each log entry retained as much as possible the citizens' own words and focused on "the point" that was stressed. Concerns had been expressed on 5x7 cards. If a card held only the words "health effects," that is, the log entry was simply those words. If a card held the question "How will this affect sensitive individuals?" concern for "effect on sensitive individuals" was recorded in the data log. Based on the log of concerns for each group, analysis focused on summarizing the local (statement level) subjects or issues.

To rigorously summarize the concerns expressed, the author utilized knowledge about understanding others' points and dialogue topics. That body of knowledge asserts that people understand others' points by tracking the more general issue, called the "global" topic or subject (Cegala, Dewhurst, Galanes, Burggraf, Thorpe, Keyton, & Makay, 1989; Tracy, 1982, 1983; Reinhart, 1981). "Local" or statement level topics are made coherent, in a complex conversation, by their organization within global issues or topics, that is. Here, the strategy used was to group local concerns in more general, logical global concern groupings, to render the concerns intelligible as a whole, but retaining as well the individual voice that give the global topic labels greater meaning. For the same reason, the labels given to the subject or issue clusters are expressions used by individuals in the study.

Example of Local Issues and Summary Global Issue

General (global) versus Local (statement-level) expression of concern	
Long term health effects	Long term risks of ultrafine pigments, nano cosmetics, wearing nanopants Breakthroughs that turn into disasters Biodegradable nanostructures' effect on food chain

Summaries were first produced for each group. The group summaries were then merged to produce a cross-case summary for each region, in order to locate shared concerns across all the groups. The most frequently mentioned concerns were not reduced further (military concerns and long term health concerns are two examples). Lower frequency concerns were reexamined and if possible, grouped under a slightly more general issue label, in order to retain the most concerns possible while reducing complexity to a manageable level. The focus of analysis at this level, thus, was on aggregating concerns as topical issues rather than on tracing arguments.[ii] Tracing arguments could be a valid way to understand premises and choices, but for this study, concerns or issues were investigated as global issues. The summarization process was intended to discover shared concerns across all participants.

[i] Sources for examining developing applications and research discoveries include industry magazines such as *SmallTimes*, on line at http://smalltimesmedia.com and *Nanotechnology Now*. Other sources regularly reporting nanoscience developments include *Science Daily* (www.sciencedaily.com), *Nature, PR Newswire, The Age*, and *The Scientist*. A historical narrative of nanotecology's development is in Regis, E. (1995). Nano. The emerging science of nanotechnology: remaking the world-molecule by molecule. Boston: Little, Brown.

[ii] Whereas a topic is the substantive subject of a sentence, paragraph, or discussion, an "argument" is a more complex feature of communication, as well as a term with multiple uses and meanings (O'Keefe, 1977). In O'Keefe's formulation, "argument$_1$" is defined as a statement-level argument; "Jenny's hair is red" is an example of argument$_1$, a statement that makes an argument for or against something. "Argument$_2$" locates a different sense of the term argument, where 'argument' is a type of interaction between several parties, an interactive exchange including claims, counterclaims, rebuttals, etc. In yet another common meaning of the term argument, the "argumentative case" is a complex line of argument (Rieke & Sillars, 1997). A line of argument is a collection of premises put forward by one author, making a case for a particular conclusion.

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